DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Memorandum

Date SEP 29 1995

From Director, Office of Device Evaluation (HFZ-400)
Center for Devices and Radiological Health (CDRH)

Subject Premarket Approval of CareLink Corporation
CareFone™ Home Uterine Activity Monitoring System, Model 2001

To The Director, CDRH
ORA _____

ISSUE. Publication of a notice announcing approval of the subject PMA.

FACTS. Tab A contains a FEDERAL REGISTER notice announcing:

(1) a premarket approval order for the above referenced medical device (Tab B); and

(2) the availability of a summary of safety and effectiveness data for the device (Tab C).

RECOMMENDATION. I recommend that the notice be signed and published.

Susan Alpert, Ph.D., M.D.

Attachments

Tab A - Notice
Tab B - Order
Tab C - S & E Summary

DECISION

Approved ✓ Disapproved _____ Date 6-5-94

Prepared by Kathy Daws-Kopp, CDRH, HFZ-470, 9/22/95, 594-1180

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P910063

DRAFT

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

[DOCKET NO. _____]

Carelink Corporation: PREMARKET APPROVAL OF CareFone™ Home Uterine Activity Monitoring System, Model 2001

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by CareLink Corporation, Santa Ana, California 92705, for premarket approval, under section 515 of the Federal Food, Drug, and Cosmetic Act (the act), of CareFone™ Home Uterine Activity Monitoring System, Model 2001. FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter on September 29, 1995, of the approval of the application.

DATE: Petitions for administrative review by (insert date 30 days after date of publication in the FEDERAL REGISTER).

ADDRESS: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 1-23, 12420 Parklawn Drive, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Colin Pollard,
Center for Devices and Radiological Health (HFZ-470)
Food and Drug Administration
9200 Corporate Blvd.
Rockville, MD 20850

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301-594-1180.

SUPPLEMENTARY INFORMATION: On December 23, 1991, CareLink Corporation, Santa Ana, California 92705, submitted to CDRH an application for premarket approval of CareFone™ Home Uterine Activity Monitoring System, Model 2001. The device is a Home Uterine Activity Monitor and is indicated for use, in conjunction with standard high risk care, for the daily at-home measurement of uterine activity in pregnancies ≥ 24 weeks gestation for women with previous preterm delivery. Uterine activity data are displayed at a remote location to aid in the early detection of preterm labor.

In accordance with the provisions of section 515(c)(2) of the act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Obstetrics and Gynecology Devices Panel, an FDA advisory panel, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

On September 29, 1995, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

OPPORTUNITY FOR ADMINISTRATIVE REVIEW

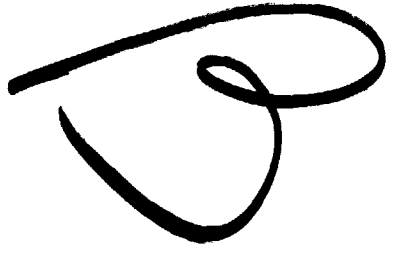
Section 515(d)(3) of the act (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act (21 U.S.C. 360e(g)), for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under part 12 (21 CFR part 12) of FDA's administrative practices and regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under 10.33(b) (21 CFR 10.33(b)). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the FEDERAL REGISTER. If FDA grants the petition, the notice will state the issue to be reviewed, the form of the review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before (insert date 30 days after date of publication in the FEDERAL REGISTER), file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h), (21 U.S.C. 360e(d), 360j(h)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: _____.

_____



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 29 1995

Ms. Susan J. Reimers
Manager, Regulatory Affairs
CareLink Corporation
1821 East Dyer Road, Suite 150
Santa Ana, California 92705-5700

Re: P910063
CareFone™ Home Uterine Activity Monitoring System, Model 2001
Filed: December 23, 1991
Amended: January 29, March 12, May 5, and August 5, 1992;
April 8, August 12, and September 21, 1993; January 11,
March 9 and 24, May 27, and September 14, 1994; March 7,
August 21, September 12, 14, 15, 19, 20, and 22, 1995

Dear Ms. Reimers:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the CareFone™ Home Uterine Activity Monitoring System, Model 2001. This device is indicated for use, in conjunction with standard high risk care, for the daily at home measurement of uterine activity in pregnancies greater than or equal to 24 weeks gestation for women with previous preterm delivery. Uterine activity data is displayed at a remote location to aid in the early detection of preterm labor. We are pleased to inform you that the PMA is approved subject to the conditions described below and in the "Conditions of Approval" (enclosed). You may begin commercial distribution of the device upon receipt of this letter.

The sale, distribution and use of this device are restricted to prescription use in accordance with 21 CFR 801.109, within the meaning of section 510(e) of the Federal Food, Drug, and Cosmetic Act (the act) under the authority of section 515(d)(1)(B)(ii) of the act. FDA has also determined that to ensure the safe and effective use of the device that the device is further restricted within the meaning of section 520(e) under the authority of section 515(d)(1)(B)(ii), (1) insofar as the labeling specifies the requirements that apply to the training of practioners who may use the device as approved in this order and, (2) insofar as the sale, distribution and use must not violate sections 502(q) and (r) of the act.

CDRH will publish a notice of its decision to approve your PMA in the FEDERAL REGISTER. The notice will state that a summary of the safety and effectiveness data upon which the approval is based is available to the public upon request. Within 30 days of publication of the notice of approval in the FEDERAL REGISTER, any interested person may seek review of this decision by requesting an opportunity for administrative review, either through a hearing or review by an independent advisory committee, under section 515(g) of the Federal Food, Drug, and Cosmetic Act (the act).

Failure to comply with the conditions of approval invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act.

You are reminded that as soon as possible, and before commercial distribution of your device, that you must submit an amendment to this PMA submission with copies of all approved labeling in final printed form.

All required documents should be submitted in triplicate, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

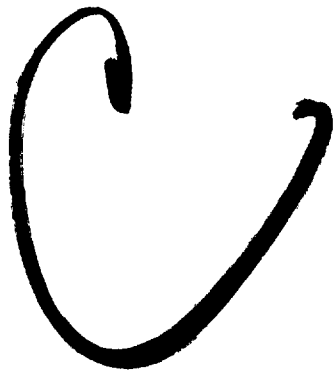
PMA Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

If you have any questions concerning this approval order, please contact Ms. Kathy Daws-Kopp at (301) 594-1180.

Sincerely yours,

Susan Alpert, Ph.D., M.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure



SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

I. GENERAL INFORMATION

Device Generic Name: Home Uterine Activity Monitor

Device Trade Name: CareFone™ Home Uterine Activity Monitoring System Model 2001

Applicant's Name and Address:

CareLink
205 Technology Drive, Suite 100
Irvine, California 92718

Premarket Approval (PMA) Application No.: P910063

Date of Notice of Approval to the Applicant: September, 29, 1995

II. INDICATIONS FOR USE

The CareLink CareFone™ Home Uterine Activity Monitoring System Model 2001 (hereinafter referred to as the CareFone™ HUAM) is indicated for use, in conjunction with standard high risk care, for the daily at-home measurement and recording of uterine activity in pregnancies ≥ 24 weeks gestation for women with previous preterm delivery. Uterine activity data are displayed at a remote location to aid in the early detection of preterm labor.

III. DEVICE DESCRIPTION

The CareFone™ HUAM 2001 system consists of the following components: The CareFone™, a special purpose computer which incorporates a telephone handset, touch-sensitive graphic video display console and integrated power supply; a tocotransducer; an elastic belt; and software for use by the patient and the monitoring center.

The patient can access the CareFone™ HUAM by insertion of a diskette into the disk drive and pressing the reset button, at which time all menus and options are available by touching the screen on the application option being selected. The tocotransducer which is positioned on the patient's abdomen with an elastic belt, senses changes in pressure caused by contractions of uterine muscles. This uterine activity is recorded by he CareFone™ HUAM, stored in memory on disk and is simultaneously available for viewing by the patient on the computer screen. After one hour of monitoring and data collection, the uterine activity data are transmitted automatically, via modem, to the monitoring center over ordinary telephone lines.

The special-purpose software for use at the receiving center is designed for an Apple Macintosh® computer, modem, and LaserWriter® printer. The primary function of this system is to receive, display, store, access and print uterine activity data computed by the CareFone™ HUAM.

IV. CONTRAINDICATIONS FOR USE, WARNINGS AND PRECAUTIONS

There are no known contraindications for the CareFone™ HUAM.

Warnings and precautions can be found in the CareFone™ HUAM labeling (See Attachment 1).

V. ALTERNATIVE PRACTICES AND PROCEDURES

Alternative practices and procedures for the monitoring of uterine contractions involved educating patients to increase their awareness of the signs and symptoms of preterm labor. This involves instructing patients to manually monitor (palpate) uterine contractions. In addition, cervical status is frequently assessed, and nursing services have been utilized to assist in the detection of preterm labor. Further, the use of other legally marketed HUAM devices for monitoring PTL has been available since 1989.

VI. MARKETING HISTORY

The CareLink HealthPhone™ TOCO Model Uterine Activity Measurement System received clearance for home monitoring of low risk pregnancies *at term* on March 11, 1988. CareLink HUAMs have not been marketed for preterm labor use in the United States or any foreign country.

VII. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

Within the studies that have been performed to date, there have been no reported adverse effects on health.

Even though the belt is easily adjustable to fit a wide range of abdominal girths, there is the possibility of mild discomfort from its use. There is also a possibility of skin irritation from abdominal contact with the transducer, although during the one-year study period, no episodes of skin irritation were reported. The potential for skin irritation is considered remote since the tocodynamometer is generally worn only 2 hours per day. In conjunction, the potential is further reduced since the patient contacting material has undergone toxicologic testing and is considered safe for skin contact.

With any electrical device there is always some potential for electric shock. The potential for electric shock while using the CareFone™ is minimal. The device was tested by Underwriters Laboratories and found to be complaint with UL 544

(Medical and Dental Equipment) and UL 1431 (Personal Hygiene and Health Care Appliances). As with any electronic device, a patient should not use the device while bathing or near water. There were no adverse events reported regarding electrical hazards, and labeling cautions the patient not to remove the housing cover or use the device while bathing or near water. In addition, the patient is cautioned not to send data via telephone modem from the Base Station to the Receiving Computer during an electrical storm.

VIII. SUMMARY OF PRE-CLINICAL STUDIES

LABORATORY STUDIES

The objectives of the laboratory studies were to test the performance of the software and hardware. This testing included development techniques used for verification of performance involving emulation of the software modules, integration testing of the modules linked together, system testing of the hardware and software, and clinical testing of the hardware and software.

CareFone™ Hardware/Software Tests. The CareFone™ 2001 HUAM was tested in stages during the development process. The hardware testing program consisted of various unit tests, integration tests, regulatory and safety agency tests, qualification tests, and a final patient-use test. The electronic hardware was tested unit-by-unit as each Printed Wiring Assembly (PWA) was developed, built, and integrated into the system.

Individual software modules comprising HUAM Version 2.1 were verified and tested as they were developed. In addition, the modules in existence prior to the development of HUAM were employed in other medical applications and were tested through many years of use.

Using CareFone™ 2001 prototype units with HUAM Version 2.1 software, a series of Design Verification Tests were conducted to verify that the product met functional specifications and to determine fine-scale performance parameters. these included tests of operation at temperature extremes, mechanical shock, emission of and susceptibility to electromagnetic interference, and computer performance. The amplification of the tocotransducer channel was tested in the linear region as well as at the overload limits using calibrated weights. Also included was a test in the home to measure performance in that environment prior to use by patients. Monitoring, transmission, and reception capability was tested.

Extensive validation, qualification, and patient-use tests were conducted on HUAM Version 2.1 software using the CareFone™ 2000 as the test platform. During this software testing phase alone, the HUAM Version 2.1 was used to monitor more than 1000 hours of uterine activity of more than 30 patients in a variety of settings.

Indy Nurse Station System Tests. Indy software modules were tested as they were developed and as they were integrated into the system. Verification consisted of walk-through of the source code for each module. Validation testing was performed according to the validation plan for each module.

Deliberate attempts to induce system failure were made during the Qualification Tests: multiple users accessed records simultaneously and the file server and the nurse station computers were deliberately disconnected during use. Over 17,000 unit-hours of multi-user operation and testing were accumulated.

ADDITIONAL STUDIES

The objectives of the additional studies were to investigate compliance with the electrical safety and FCC standards, electromagnetic compatibility standards, and other standards specified within the Premarket Testing Guidelines for Home Uterine Activity Monitors (Guide).

FCC/Electrical Safety Testing. Tests were conducted by an independent laboratory to verify that the telephone circuitry and modem complied with Federal Communications Commission (FCC) regulations. Testing was also conducted to ensure that the appropriate Underwriters Laboratories (UL) standards were met.

Electromagnetic Compatibility (EMC) Testing. Tests were conducted by an independent laboratory to establish specifications for electromagnetic compatibility. These tests included conducted emissions, radiated and conducted susceptibility, electrostatic discharge, along with magnetic fields' effects and quasi-static electric fields' effects on the operation of the device. Testing was conducted to the following standards for each test and found not to exceed the limits of the classification applicable to each standard:

Test	Standard
1.0 Conducted Emissions	CISPR II, Group I, Class B
2.0 Radiated & Conducted Susceptibility	
2.1 Fast Surges (High Energy Transients)	IEC 801-5
2.2 Radiated Susceptibility	IEC 801-3
2.3 Fast Transients (EFT)	IEC 801-4
2.4 Conducted Susceptibility	MIL-STD-461D
3.0 Magnetic Field Emissions	RE101 of MIL-STD-462D
4.0 Magnetic Fields' & Quasi-Static Electric Fields' Effects	MIL-STD-461D
5.0 Electrostatic Discharge	IEC 801-2

IX. SUMMARY OF CLINICAL STUDIES

CLINICAL FEASIBILITY STUDIES

The applicant performed clinical tests to verify that the System 37 could record, transmit, and display uterine activity data in hospital and home settings. A portion of this testing compared the monitoring of uterine activity of the CareFone™ HUAM with a commercially available perinatal monitor.

PIVOTAL CLINICAL TRIAL

The objective of this clinical study was to assess the safety and effectiveness of the CareFone™ HUAM in use with standard high risk care as an aid in the early detection of preterm labor.

Study Methods

The study was a randomized, prospective, controlled, multi-center clinical investigation. Five clinical centers were employed including the University of California (Davis, CA), University of Washington (Seattle, WA), University of Michigan (Ann Arbor, MI), St. John's Mercy Medical Center (St. Louis, MO), and Sharp Perinatal Center (San Diego, CA). The inclusion criteria for all study participants were as follows:

1. A pregnancy between 20 and 32 weeks gestation;
2. At least 1 of 12 possible risk factors under "Modified" Creasy scoring method (see list below);
3. English speaking;
4. Willing to understand and comply with the requirements of the study;
5. 15 years of age or older; and
6. Have an active touch tone telephone connection.

The exclusion criteria were as follows:

1. Substance abuse during the current pregnancy;
2. Unable to demonstrate the ability to fully comply with the study requirements;
3. Presence of fetal congenital anomalies;
4. Known indicated preterm delivery;
5. Placenta previa;
6. Incompetent cervix; or
7. Cervical dilation > 2 cm or cervical length < 2 cm.

The following 12 risk factors accounted for the entire patient population that was enrolled:

1. Multiple gestation
2. Previous preterm delivery
3. Previous preterm labor with a term delivery
4. Abdominal surgery in the current pregnancy
5. Diethylstilbestrol (DES) exposure
6. Hydramnios during the current pregnancy
7. Cone biopsy of the cervix
8. Uterine irritability
9. More than 1 second trimester abortion
10. Preterm labor in the current pregnancy
11. Cervical dilation of greater than 1 cm or effacement less than 50% at 32 weeks gestation
12. Uterine irritability

Study subjects were randomized to one of two arms: (a) standard high risk obstetrical care (Control) versus (b) use of the CareFone™ HUAM for two single hour sessions per day plus standard high risk obstetrical care (Monitored) to determine if the addition of the CareFone™ HUAM to standard high risk care resulted in the detection of preterm labor (PTL) at significantly less dilation.

All subjects were educated according to the March of Dimes (pamphlet no. 33-205-03) guidelines regarding self-palpation of the uterus and other signs and symptoms of PTL. This education was not administered prior to 20 weeks gestation. Randomization into study and control arms occurred after this education

Each subject presented for a routine clinical visit every four weeks up to 30 weeks gestation and every two weeks thereafter until 36 completed weeks of gestation. Standard gynecologic examinations were conducted and medical histories were taken to assess potential complications.

Each subject was instructed to determine the frequency of uterine contractions twice daily either by self-palpation or by using the CareFone™. If contraction frequency was four or more contractions per hour, subjects were instructed to seek appropriate medical intervention in the form of an unscheduled or non-routine visit.

Procedures for management of subjects presenting for non-routine visits were standardized across the five centers. A history was taken regarding their presenting symptoms, uterine activity was monitored, cervical examinations to rule out or confirm PTL were performed if deemed necessary by the clinician, and hydration and tocolytic medications were administered, if necessary.

Patient Assessments

The diagnosis of preterm labor was determined by clinical examination under the following preterm labor study definition:

a. Gestational age between 20 and 36 completed weeks;

b. Documented uterine contractions of greater than or equal to four contractions per hours; and

c. Documented cervical change in either dilation or effacement above baseline values or a cervical exam revealing 2 cm or more of cervical dilation with cervical length of less than 2 cm.

No sham monitoring was conducted in the unmonitored group, and the protocol did not standardize the use of specific medical interventions for PTL such as the frequency of bedrest, cervical examinations, or specific tocolytic regimens.

The outcome measures for this study were:

Primary

1. Cervical dilation/change at time of PTL diagnosis;

Secondary

2. Gestational age at delivery; and
3. Days gained from PTL to delivery.

Study Population

This investigation utilized a sequential sampling strategy to recruit the total subject population. At each clinical site, all patients who presented for a prenatal visit were assessed for their level of PTL risk and as to whether they met the other inclusion and exclusion criteria for the study. Seven hundred and twelve (712) pregnant patients were screened for potential enrollment. Three hundred and fifty-eight (358) pregnant patients, determined to be at risk for PTL, agreed to participate and were enrolled in the study.

Randomization achieved a nearly equal balance of subject numbers in each treatment group (i.e., 180 monitor and 178 control). One hundred and fifty (150) single gestation deliveries occurred in the monitor group and 147 in the control group. Thirty (30) and 31 multiple gestation deliveries occurred in the monitor and control groups, respectively. The population of women with a previous preterm delivery was comprised of 52 monitored group patients and 58 control group patients.

712 Subjects Screened			
358 Total Subjects Enrolled			
61 Multiple Gestation		297 Singletons	
31 Control	30 Monitored	147 Control	150 Monitored
12 PTL Dx	15 PTL Dx	27 PTL Dx	38 PTL Dx
110 Subjects Enrolled with Previous Preterm Delivery			
58 Control		52 Monitored	
2 Multiple	56 Singleton	1 Multiple	51 Singleton
13 PTL Dx		17 PTL Dx	

At FDA request, two monitored subjects (one singleton and one multiple gestation) were removed from the analysis for failure to meet the protocol definition of PTL. Exclusion of these patients from the analysis did not change the conclusion drawn from the clinical study.

Safety and Effectiveness

The safety and effectiveness of the CareLink CareFone™ HUAM was based upon a comparison of cervical characteristics and other factors associated with pregnancy among monitored and control subjects at risk for PTL. For the total study population, monitored women had less cervical dilation at the time of diagnosis of PTL when compared with the control group (Table 1).

TABLE 1

Mean (SD) Cervical Dilation (cm) at Time of PTL Diagnosis, Total Study Population

Monitored (N = 53)	Control (N = 39)	p-value
1.5 ± 1.5	2.25 ± 2.0	0.05

If tocolytic therapy for PTL is initiated before cervical dilation reaches 2 cm, it is considered more likely to be successful. The number of subjects from the monitored and control group with < 2 cm in dilation at the time of diagnosis of PTL were compared. The CareFone™ HUAM was effective in identifying a greater proportion of subjects with PTL at this lesser degree of cervical dilation (Table 2).

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TABLE 2

Percent with < 2 cm Dilated at the Time of PTL Diagnosis, Total Study Population

Monitored (N = 53)	Control (N = 39)	p-value
64.2%	53.9%	0.39

For the total study population that experienced PTL, 34 of 53 (64.2%) monitor subjects were diagnosed with PTL at less than 2.0 cm cervical dilation compared to 21 of 39 (53.9%) control subjects. This increased likelihood of being less than 2 cm dilated at the time of diagnosis of preterm labor while not statistically significant ($p = 0.39$), is consistent with a trend for earlier detection of PTL in the monitored group. Further the difference is more significant for those subjects diagnosed with dilation < 1 cm at time of PTL diagnosis (35.8% verses 7.7%, $p = 0.002$).

The primary outcome measure for this study was cervical status at time of PTL diagnosis. Since some patients had cervical dilation before the onset of labor, a comparison of the change in dilation from the examination immediately before the onset of preterm labor was completed (Table 3).

TABLE 3

Mean (SD) Change in Cervical Dilation (cm) at Time of PTL Diagnosis
Total Study Population

Monitored (N = 53)	Control (N = 39)	p-value
1.3 ± 1.4	1.9 ± 2.0	NS

Of the enrolled and randomized study subjects who met the entry criteria with PPTD and experienced an event of preterm labor, monitored women had less cervical dilation at the time of diagnosis of PTL when compared with the control group (Table 4).

TABLE 4

Mean (SD) Cervical Dilation (cm) at Time of PTL Diagnosis, Subjects with PPTD

Monitored (N = 17)	Control (N = 13)	p-value
1.4 ± 1.1	2.4 ± 2.1	0.16

The number of subjects enrolled with PPTD from the monitored and from the control group with < 2 cm in dilation at the time of diagnosis of PTL were compared (Table 5).

TABLE 5

Percent with < 2 cm Dilated at the Time of PTL Diagnosis, Subjects with PPTD

Monitored (N = 17)	Control (N = 13)	p-value
58.8%	53.8%	1.0

Again, the primary outcome measure for this study was cervical status at time of PTL diagnosis. Since some patients had cervical dilation before the onset of labor, a comparison of the change in dilation from the examination immediately before the onset of preterm labor was completed (Table 6).

TABLE 6

Mean (SD) Change in Cervical Dilation (cm) at Time of PTL Diagnosis
Subjects with PPTD

Monitored (N = 17)	Control (N = 13)	p-value
0.9 ± 0.9	1.7 ± 2.1	0.19

X. CONCLUSIONS DRAWN FROM THE STUDIES

The CareFone™ HUAM can be used to detect, record, and transmit uterine contraction data to qualified medical professionals for evaluation. Overall analysis of the study population (N_m = 53, N_c = 39) revealed that there was a statistically significant difference between the mean cervical dilation of the monitored population (1.5 cm) verses the control population (2.25 cm) at diagnosis of PTL. Subgroup analysis (N_m = 17, N_c = 13) did not reveal a statistically significant result ($p = 0.16$) for the mean cervical dilation of the monitored population (0.9 cm) verses the control population (1.7 cm). It is believed that the results are clinically meaningful and the nonsignificant results are due to the small sample size. These differences observed between the two groups, although not statistically significant, are of the same order of magnitude as the total study population.

It should be noted that the CareFone™ HUAM™ was used in conjunction with a standard care regimen for women at high risk of preterm labor. Standard care as used in this study consisted of routine clinical visit every four weeks up to 30 weeks gestation and every two weeks thereafter until 36 completed weeks of gestation. This care, which did not include daily nursing contact, served as the control for the study.

Based on this outcome data, limitations in the study design did not allow for conclusions regarding the effects of treatment, sham monitoring, frequency of cervical exams, the potential benefits of frequent nursing contact, or the potential benefits of the CareFone™ HUAM when used as an addition to obstetrical care that differs significantly from the care provided as part of this study.

XI. PANEL RECOMMENDATION

Pursuant to section 515(c)(2) of the Food, Drug and Cosmetic Act (the Act), as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Obstetrics and Gynecologic Devices Panel, an FDA advisory panel, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel. However, at three consecutive Panel meetings on April 29-30, 1993; September 1-2, 1994; and April 24, 1995, FDA sought guidance on several general issues relating to this and other PMAs and to the use of HUAM devices. The issues discussed with the Panel consisted of inclusion of subjects at early and late gestational ages (GA), target study populations, clarifications on acceptable definitions of PTL, prophylactic tocolysis use, minimum standard care, cervical dilation as a primary endpoint, inclusion of specific subgroups in the analysis, significance of the results of specific subgroups, the quality of the data transmission, labeling and promotional claims, post approval studies, and the impact of other studies showing negligible effect. The issues and Panel discussion are presented in more detail below.

On April 29-30, 1993, the Panel addressed generic HUAM study design questions, as follows:

(1) **Intra- and Inter-observer Variance for Cervical Exams.** (This addresses the variance that occurs in these inexact measurements between observers and between exams for the same observer). The Panel concluded that, within reason, this must be tolerated because there are no known alternatives to this system of clinical management.

(2) **Definition of Preterm Labor.** In several variations of this discussion, it was determined that nearly any definition, within reason, is acceptable if it is applied equally to study and control arms, regardless of whether the subject delivers in a timely manner.

(3) **Prophylactic Tocolysis use.** It was noted that prophylactic tocolysis (i.e., use of tocolytics before PTL is diagnosed) might influence the primary study endpoint, cervical dilation at PTL diagnosis. The Panel indicated that cases where tocolysis is used, both before and after PTL diagnosis, should not be excluded, as long as such use is evenly balanced between the control and study arm.

(4) **Monitoring Before 24 Weeks Gestation.** Given that this is arguably prior to the gestational age where intervention is successful or delivery of a viable fetus is likely, FDA asked the Panel whether these subjects should be included in the analysis. There was discussion concerning the reflection of the study population in the labeling.

(5) **Medically Indicated Preterm Deliveries.** At one point, it was suggested that medically indicated preterm deliveries should be excluded from analysis because these patients could not have benefited from such HUAm monitoring. The Panel indicated that it would be appropriate to include these subjects in analysis for cervical dilation, but they should be excluded from the analysis for perinatal outcome.

(6) **Subgroup Analysis by Gestational Age.** It was noted that, in a significant portion of the study, PTL diagnosis occurred after 34 weeks gestation. Subgroup analysis of the women diagnosed in PTL before this point might be very useful. The Panel commented that such analysis was beyond the scope of the original hypothesis, and thus, should not be required.

(7) **Data Transmission Quality.** The FDA asked the Panel to comment on appropriate review criteria for assessing the quality of data transmission resulting from the combination of transducer, signal processing, telephone transmission, and data display. The Panel commented that the resulting display of the uterine contraction tracing should not be so distorted as to cause misinterpretation.

On September 2, 1994, the Panel addressed generic HUAM study design questions, as follows:

(1) **Cervical Dilation as a Primary Endpoint.** FDA argued that diagnosis of PTL can only be truly confirmed retrospectively. Thus, FDA posed, the use of cervical dilation in the definition of PTL results in a problem determining the disposition of subjects who do not continue promptly from PTL diagnosis to delivery. The Panel agreed that this study endpoint has ascertainment bias, but any other treatment of this data would undermine the prospective nature of the study. Furthermore, the Panel acknowledged that this endpoint is compatible with clinical practice and no better alternative could be identified.

(2) **Standard Care for High-Risk Pregnancies.** FDA questioned whether the control arm of the study received adequate care, in terms of detecting PTL. If inadequate, this could lead to a misleading comparison between the monitor and control groups. The Panel acknowledged the widely varying management regimens at different clinical centers. However, they did not find that any of the current regimens used for control patients were substandard.

(3) **Labeling Claims.** As evidenced by reduced cervical dilation at diagnosis, HUAMs are useful for the early detection of preterm labor. FDA suggested that the Panel discuss the implied claims for the product and any resulting modifications to the consumer labeling. They discussed potential labeling changes, but did not come to any majority conclusions.

(4) **Postapproval Studies.** FDA proposed the possibility of addressing important clinical issues that might not have been addressed in the premarket studies in a post market study. The Panel discussed the various inadequacies brought up during the discussion of question one as potential concerns for a postapproval study. However, they did not come to a consensus on any specific type of postapproval study.

On April 24, 1995, another Panel meeting was held to discuss a recent publication on a randomized controlled study that showed monitoring had no effect when compared with a sham control containing frequent nursing contact. At this meeting the Caremark study[1] was formally presented. Representatives from industry and the general public were given an opportunity to comment.

Additionally, the Panel was given a history of HUAM regulation and addressed generic HUAM study design questions, as follows:

(1) **Preterm Labor Definition - Postdiagnosis Failure to Proceed to Labor.** This question pertains to the situation where PTL is diagnosed and no intervention is prescribed, but Delivery does not follow in a timely fashion (within 2 weeks). Should the diagnosis of PTL stand? Some members of the Panel opined that PTL could stop. It was determined that the effect would be even in both control and treatment arms and the diagnosis should stand.

(2) **Study Populations.** FDA questioned whether specific socio-economic groups (such as tobacco smokers) should be excluded or included because of their possible effects on the data. The Panel determined that FDA should not mandate that specific target populations be included in the study populations, other than those at risk for PTL.

(3) **Affect of Other Studies That Showed No Added Effect from HUAM Use.** FDA asked the Panel about the impact of the Caremark study on the labeling claims of other HUAM devices. The Panel stated that few issues have a record of completely positive results. Specific changes to the labeling requirements were not recommended.

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[1] Devoe, et al. A Multicenter Randomized Controlled Trial of Home Uterine Monitoring (HUAM): Active Vs. Sham Device. American Journal of Obstetrics and Gynecology, SPO Abstracts 1995;172(1):253.

XIII. CDRH DECISION

CDRH evaluated the concerns identified with the CareFone™ HUAM study, in light of the comments and guidance obtained from the advisory Panel. In particular, CDRH concurred with the Panel's decision that use of the PTL definition was acceptable as long as the definition was consistently applied to all study arms. CDRH removed from the data analysis those patients that did not appear to meet the definition of PTL. In addition, the applicant was required to submit information to address the issue of potential bias in the use of tocolytics. CDRH determined that there was not sufficient evidence to conclude that bias existed.

Based upon a review of the data contained in the PMA, CDRH determined that the CareFone™ Home Uterine Activity Monitoring System Model 2001 has been shown to be effective for the indications as specified in the labeling. FDA issued an approval letter on September 29, 1995.

The applicant's manufacturing facility was inspected on August 31, 1994, and was found to be in compliance with the Good Manufacturing Practice Regulations.

XIV. APPROVAL SPECIFICATIONS

Directions for use: See attached Labeling

Warnings, Hazards to Health from the Use of the Device: See indications, contraindications, warnings, precautions and adverse reactions in the attached labeling.

Conditions of Approval: CDRH Approval of this PMA is subject to full compliance with the conditions described in the approval order.

CareFone™ Home Uterine Activity Monitoring System

Physician Information Sheet

CAUTION

United States Federal law restricts this device to sale, distribution, or use by or on the order of a physician. The device is further restricted with respect to the training of ~~medical practitioners~~ physicians who may use the device.

1.0 DEVICE DESCRIPTION AND FEATURES

1.1 The CareLink CareFone™ Home Uterine Activity Monitoring System, Model 2001 (hereinafter referred to as the CareFone HUAM) consists of the following components: the CareFone™, a special purpose computer which incorporates a telephone handset touch-sensitive graphic video display console and integrated power supply; a tocotransducer; an elastic belt; and software for use by the patient and the monitoring center. The CareFone™ HUAM is designed to record, compute, and transmit uterine activity data, via a phone line modem, to the monitoring center.

2.0 INDICATIONS FOR USE

2.1 The CareLink CareFone™ HUAM is indicated for use, in conjunction with standard high risk obstetrical care, for the daily at-home measurement and recording of uterine activity in pregnancies ≥ 24 weeks gestation for women with previous preterm delivery. Uterine activity data are displayed at a remote location to aid in the early detection of preterm labor (PTL).

3.0 CONTRAINDICATIONS

3.1 There are no known contraindications to home uterine monitoring.

4.0 WARNINGS

4.1 This device will not prevent or predict the onset of preterm labor nor will it prevent the occurrence of preterm birth. The CareFone™ HUAM monitors uterine activity and provides this information to the physician for assessment and, if necessary, intervention.

4.2 Close supervision is necessary when this product is used near children. All users should follow the instructions provided in their manual to ensure proper use of the device.

4.3 Properly use the grounding plug; improper use can result in a risk of electric shock. If the use of an extension cord is necessary, use only a cord that has a 3 blade grounding plug. Use only an outlet (with a temporary adapter if necessary) that is properly installed and grounded.

4.4 To reduce the risk of electrocution: Do not use while bathing. Do not place or store product where it can fall or be pulled into a tub or sink. Do not place in or drop into water or any other liquid. Do not reach for a product that has fallen into water or any liquid. Unplug it immediately.

4.5 Do not operate the CareFone™ HUAM if it has a damaged cord or plug, if it is not working properly, if it has been dropped or damaged, or dropped into water or any other liquid. CareLink will arrange for the repair or replacement of the CareFone™ HUAM.

4.6 Keep the cord away from heated surfaces.

5.0 PRECAUTIONS

5.1 Do not block the air openings on the bottom of the CareFone™ HUAM, or place it on a soft surface, such as a bed or couch. Keep the air openings free of lint or hair. Never drop or insert any foreign object into any opening.

5.2 Do not use the CareFone™ HUAM outdoors or expose it to direct sunlight, rain, or moisture. Do not operate where aerosol products are being used or when oxygen is being administered.

5.3 There is the possibility of mild discomfort from the belt; it can be adjusted, however, to fit a wide range of abdominal girths.

5.4 Patients without a telephone will need special arrangements made for the transmission of the monitoring data.

5.5 The patient should not send data during an electrical storm with the transducer belt in place and the telephone line plugged in. A lightening strike could cause the information to be lost in transmission or damage to the equipment could occur. Recording can be completed during an electrical storm, but transmission of the data should be delayed until the belt and transducer are removed from the patient.

5.6 Patients with acute psychiatric disorders may not be able to comply with monitoring.

6.0 ADVERSE EFFECTS OF THE DEVICE ON HEALTH

6.1 To date, no adverse reactions have been reported concerning the use of the CareFone™ HUAM.

6.2 As with any electrical device, the CareFone™ HUAM should not be used while bathing or around water as an electrical shock hazard is present.

6.3 The tocodynamometer or sensor may possibly cause skin irritation. The sensor is generally worn two hours per day. To date there have been no reports of skin irritation.

7.0 DIRECTIONS FOR USE

7.1 After prescription of the CareFone™ HUAM by a physician, the patient should be educated regarding the signs and symptoms of preterm labor and the operation of the CareFone™.

7.2 The patient must receive instructions regarding the proper operation of the CareFone™ HUAM from a qualified technician employed by CareLink and/or through an instructional videotape, and/or through the CareFone™ User's Guide which accompanies every CareFone™.

7.3 The patient should be instructed by her physician to monitor her uterine activity for one hour twice each day, usually in the morning and in the evening. The patient should be reclining in the left lateral recumbent position during the data collection period. The patient should be instructed to monitor her uterine activity at any other time that she may perceive uterine activity throughout the day or night. All uterine activity monitoring data are transmitted automatically at the conclusion of each monitoring session.

8.0 HOW SUPPLIED

8.1 The CareFone™ HUAM is provided to patients by CareLink upon prescription of a physician. The data collected by the CareFone™ HUAM are transmitted to a monitoring center where uterine activity data are reviewed by trained perinatal nurses and communicated to physicians per physicians' orders.

9.0 CLINICAL STUDIES

9.1 Study Methods

A randomized, prospective multicenter clinical investigation was undertaken to evaluate the reasonable safety and effectiveness of the CareFone™ HUAM as an aid to the clinician in the early diagnosis of PTL. Five clinical centers were

employed, enrolling a total of 358 subjects. The inclusion criteria for all study participants allowed for enrollment of women with a pregnancy between 20 and 32 weeks gestation and one or more of various risk factors, based on a modified Creasy scoring method. A subset, 110 subjects, was enrolled with previous preterm delivery as a risk factor.

Study subjects were randomized to one of two arms: (a) standard high risk obstetrical care (Control) versus (b) use of the CareFone™ HUAM for two single hour sessions per day plus standard high risk obstetrical care (Monitored) to determine if the addition of the CareFone HUAM to standard high risk care resulted in the detection of preterm labor (PTL) at significantly less cervical dilation.

All subjects were educated according to the March of Dimes (pamphlet no. 33-205-03) guidelines regarding self-palpation of the uterus and other signs and symptoms of PTL. Randomization into study and control arms occurred after this education. Each subject presented for a routine clinical visit every four weeks up to 30 weeks gestation and every two weeks thereafter until 36 completed weeks of gestation. Standard gynecologic examinations were conducted and medical histories were taken to assess potential complications.

Each subject was instructed to determine the frequency of uterine contractions twice daily either by self-palpation or by using the CareFone™ HUAM. If contraction frequency was four or more contractions per hour, subjects were instructed to seek appropriate medical intervention in the form of an unscheduled or non-routine visit.

The diagnosis of preterm labor was determined by clinical examination under the following preterm labor study definition: gestational age between 20 and 36 completed weeks; documented uterine contractions of greater than or equal to four contractions per hour; and documented cervical change in either dilation or effacement above baseline values or a cervical exam revealing 2 cm or more of cervical dilation with cervical length of less than 2 cm.

9.2 Study Conclusions

Over all analysis of the study population ($N_m = 53$, $N_c = 39$) revealed that there was a statistically significant difference between the mean cervical dilation of the monitored population (1.5 cm) versus the control population (2.25 cm) at diagnosis of PTL. Subgroup analysis ($N_m = 17$, $N_c = 13$) did not reveal a statistically significant result ($p = 0.16$) for the mean cervical dilation of the monitored population (0.9 cm) versus the control population (1.7 cm). It is believed that the results are clinically meaningful and the nonsignificant results are due to the small sample size. These differences observed between the two groups,

although not statistically significant, are of the same order of magnitude as the total study population.

It should be noted that the CareFone™ HUAM was used in conjunction with a standard care regimen for women at high risk of preterm labor. Standard care as used in this study consisted of routine clinical visit every four weeks up to 30 weeks gestation and every two weeks thereafter until 36 completed weeks of gestation. This care, which did not include daily nursing contact, served as the control for the study.

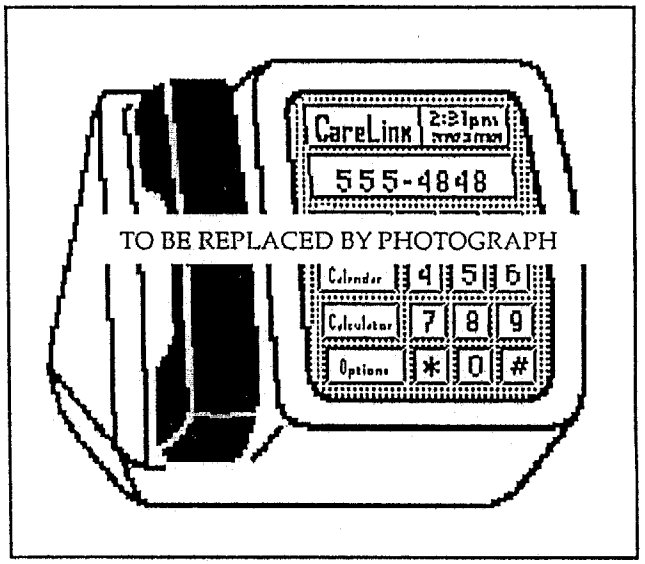
9.3 Study Limitations

Based on this outcome data, limitations in the study design did not allow for conclusions regarding the effects of treatment, sham monitoring, frequency of cervical exams, the potential benefits of frequent nursing contact, or the potential benefits of the CareFone™ HUAM when used as an addition to obstetrical care that differs significantly from the care provided as part of this study.

CareLink
a division of Tokos Medical Corporation
1821 East Dyer Road, Suite 150
Santa Ana, California 92705

PBU-00031 Rev. D

DIRECTIONS FOR USE: CAREFONE™ HOME UTERINE ACTIVITY MONITOR



CareLink

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

INDICATIONS FOR USE: The Carefone™ device is indicated for use, in conjunction with standard high risk care, for the daily at-home measurement and recording of uterine activity in pregnancies ≥ 24 weeks gestation for women with previous preterm delivery. Uterine activity data are displayed at a remote location to aid in the early detection of preterm labor (PTL).

CONTRAINDICATIONS: There are no known contraindications to home uterine monitoring.

OPERATING CONDTIONS: Use of the Carefone HUAM is recommended at room temperatures ranging from 50° F to 104° F, and humidity ranges of 10% to 95% relative humidity.

TABLE OF CONTENTS

IMPORTANT SAFEGUARDS

The Carefone HUAM should be used only with an electrical service which has been determined to be suitable to ensure electrical safety requirements are met.

When using electrical products, especially when children are present, basic safety precautions should always be followed.

WARNINGS: This device will not prevent or predict the onset of preterm labor nor will it prevent the occurrence of preterm birth. The CareFone™ HUAM monitors uterine activity and provides this information to the physician for assessment and, if necessary, intervention.

Close supervision is necessary when this product is used near children. All users should follow the instructions provided in their manual to ensure proper use of the device.

Properly use the grounding plug; improper use can result in a risk of electric shock. If the use of an extension cord is necessary, use only a cord that has a 3 blade grounding plug. Use only an outlet (with a temporary adapter if necessary) that is properly installed and grounded. See *Grounding Instructions* in Tab 1.

To reduce the risk of electrocution: Do not use while bathing. Do not place or store product where it can fall or be pulled into a tub or sink. Do not place in or drop into water or any other liquid. Do not reach for a product that has fallen into water or any liquid. Unplug it immediately.

Do not operate the CareFone HUAM if it has a damaged cord or plug, if it is not working properly, if it has been dropped or damaged, or dropped into water or any other liquid. CareLink will arrange for the repair or replacement of the CareFone HUAM.

Keep the cord away from heated surfaces.

PRECAUTIONS: Do not block the air openings on the bottom of the CareFone HUAM or place it on a soft surface such as a bed or couch. Keep the air openings free of lint or hair. Never drop or insert any foreign object into any openings.

Do not use the CareFone HUAM outdoors or expose it to direct sunlight, rain, or moisture. Do not operate where aerosol products are being used or when oxygen is being administered.

There is the possibility of mild discomfort from the belt; it can be adjusted, however, to fit a wide range of abdominal girths.

Patients without a telephone will need special arrangements made for the transmission of the monitoring data.

The patient should not send data during an electrical storm with the transducer belt in place and the telephone line plugged in. A lightening strike could cause the information to be lost in transmission or damage to the equipment could occur. Recording can be completed during an electrical storm, but transmission of the data should be delayed until the belt and transducer are removed from the patient.

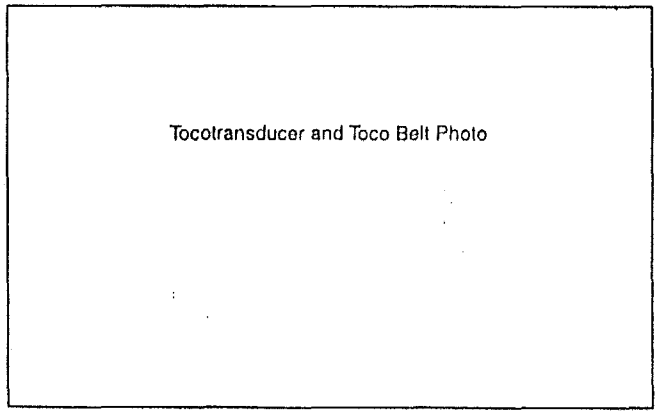
Patients with acute psychiatric disorders may not be able to comply with monitoring.

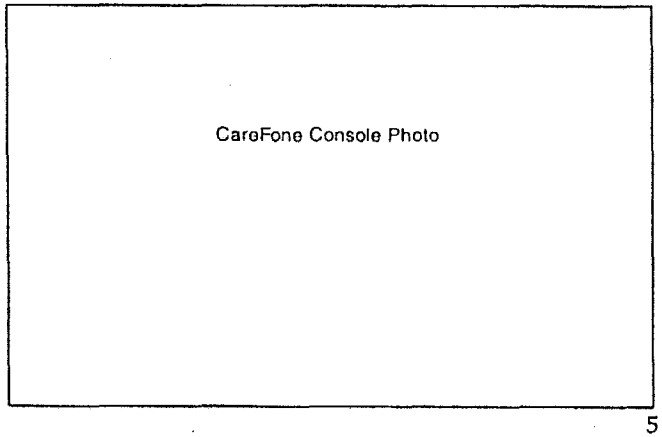
ADVERSE REACTIONS: To date, no adverse reactions have been reported concerning the use of CareFone HUAM.

The tocodynamometer or sensor may possibly cause skin irritation. The sensor is generally worn two hours per day. To date there have been no reports of skin irritation.

DESCRIPTION OF THE CAREFONE™ HUAM

Your CareFone HUAM consists of a tocotransducer, a toco belt, and a console. The CareFone console is a combination telephone and video screen.





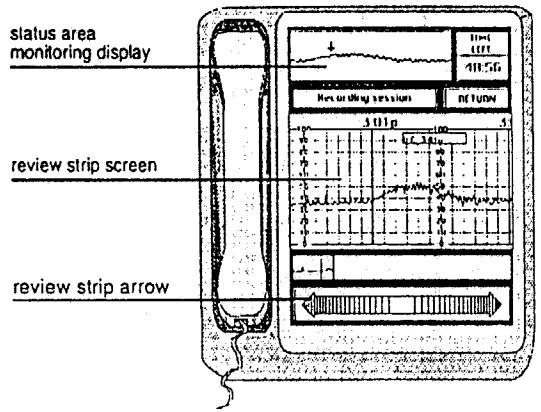
HOW THE CAREFONE™ HUAM WORKS

The uterus (womb) is made up of three layers of muscles. When the muscles tighten and push out and then relax, this is called *uterine activity*. Women can sometimes feel their uterus tighten (contract) and relax. Other times women do not feel this activity.

The tocotransducer is a pressure-sensitive device which senses the muscles of the uterus tightening, pushing out, and relaxing. The CareFone console records this information from the tocotransducer.

A pregnant woman places the tocotransducer on the skin over her uterus. When the uterine muscles push out and feel tight, the tocotransducer picks up these changes and records them. These changes appear as hills and valleys on the CareFone screen.

Uterine activity appearing on both the status area monitoring display and the review strip screen



Where Does the Monitoring Information Go?

One hour of monitoring uterine activity is called a session. At the end of each session, the CareFone™ console automatically sends the information about your uterine activity to a monitoring center. The monitoring information travels over the telephone lines to your monitoring center's computers. Your monitoring session is reviewed after it is received at the monitoring center.

If the monitoring center has any concerns or questions about your session, they will call you. If you have any problems or questions, please call your monitoring center.

If you would like to review your session with someone at the monitoring center, use your CareFone telephone to call your monitoring center. Your session can be reviewed on the computer at your monitoring center while you review it on your video screen at home.

When Should You Monitor?

Your doctor will prescribe a monitoring plan for you. For example, your doctor may order monitoring twice a day. You might monitor for one hour in the morning and for one hour in the evening.

Your doctor will tell you and your nurse how many contractions or how much activity is "too much". Too much uterine activity is generally four or more contractions per hour. If you feel or see "too much" uterine activity, call your monitoring center immediately.

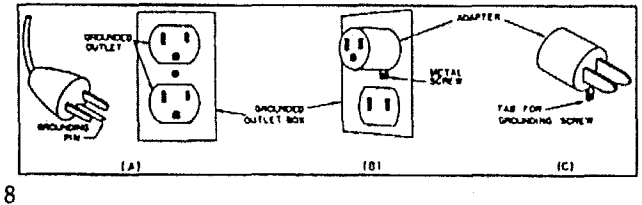
SETTING UP THE CAREFONE™ HUAM

The following steps and the diagram on the next page explain how to set up the CareFone HUAM. Check that the CareFone HUAM is properly installed before you begin to monitor your uterine activity.

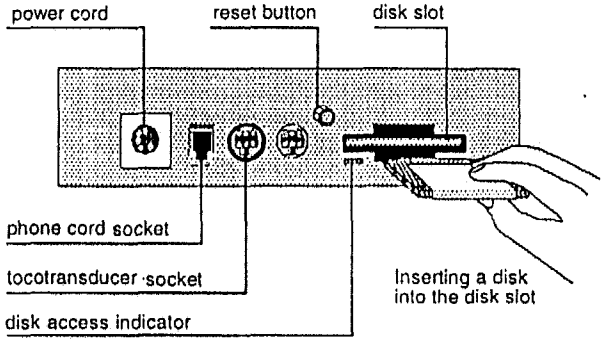
1. Place the **CareFone console** on a stable, hard, flat surface. Do not place it on a soft surface like a bed, couch or carpeting that could block the air openings.

Place Photo Here

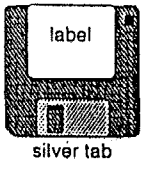
2. Plug the AC power cord into a 3-blade wall outlet. See *Grounding Instructions* in Tab 1.



View of the Back of the CareFone™ Console



3. Plug one end of the **phone cord** into the CareFone phone cord socket. Plug the other end into the phone jack on the wall.
4. Plug the **tocotransducer cord** into the round tocotransducer socket on the back of the CareFone console. Rotate the tocotransducer plug to match the silver pins in the plug with the holes in the socket, and push it gently into the socket.
5. Place the desired **diskette** into the disk slot on the back of the CareFone console. Put the silver tab of the diskette into the slot first, with the printed label facing up. Push the diskette in until you hear it "click" into the locked position.



6. Push the black **reset** button to start the program. Each time you change diskettes, you will need to push the **reset** button again.

UTERINE ACTIVITY MONITORING INSTRUCTIONS

The following instructions explain how to monitor your uterine activity with the CareFone™ HUAM. Make yourself comfortable lying on your side. Each session takes one hour to complete.

After you have inserted the *Home Uterine Activity Monitoring* diskette into the CareFone disk drive slot, you need to touch words or buttons on the video screen in a certain order.

Remember to gently touch your selection on the video screen with one finger, wait for the item to turn black, and then remove your finger straight away from the screen. The picture on the video screen will change after you lift your finger off the word or the button.

If the Home Uterine Activity Monitoring diskette is already in the diskette slot and the reset button has been pressed, return to the Telephone screen if necessary, and start with step 2. If not, start with step 1.

Steps 1 to 3: Uterine Monitoring Instructions

1. Insert the *Home Uterine Activity Monitoring* diskette into the disk slot opening. Push the reset button on the back of the CareFone console. Touch the TOUCH TO CONTINUE button when the Startup screen appears.
2. Touch Options. (Note: unless instructed otherwise, always make sure the next-to-last button on the Options screen says AUTOMATIC SEND. If it says MANUAL SEND, touch it to change it to AUTOMATIC SEND.)
3. Touch MONITORING.

Adjusting the Tocotransducer

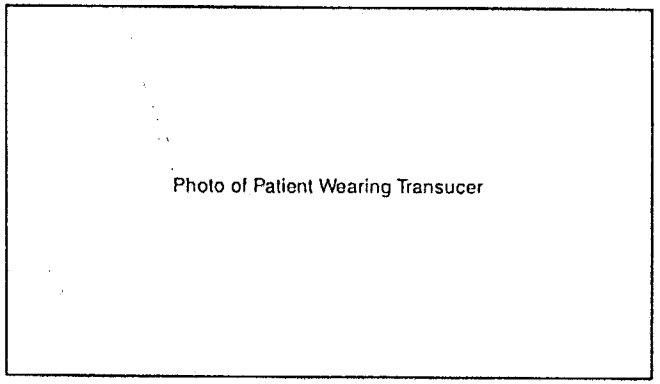
Put on the toco belt and adjust the tocotransducer. If you would like on-screen information about how to adjust your belt and use the tocotransducer, touch the INFO button for instructions similar to the information in this section of this manual. If you like, it is acceptable to wear clothing over the belt. DO NOT wear clothing between the tocotransducer and your abdomen.

Step 4: Uterine Monitoring Instructions

4a. Button one end of the toco belt onto the pointed knob of the tocotransducer.

4b. Place the large flat knob of the tocotransducer against the skin of your belly, as instructed.

4c. Wrap the toco belt around your waist. Button the loose end of the toco belt onto the pointed knob of the tocotransducer so that it is snug and feels comfortable.



Toco Belt Too Loose or Too Tight?

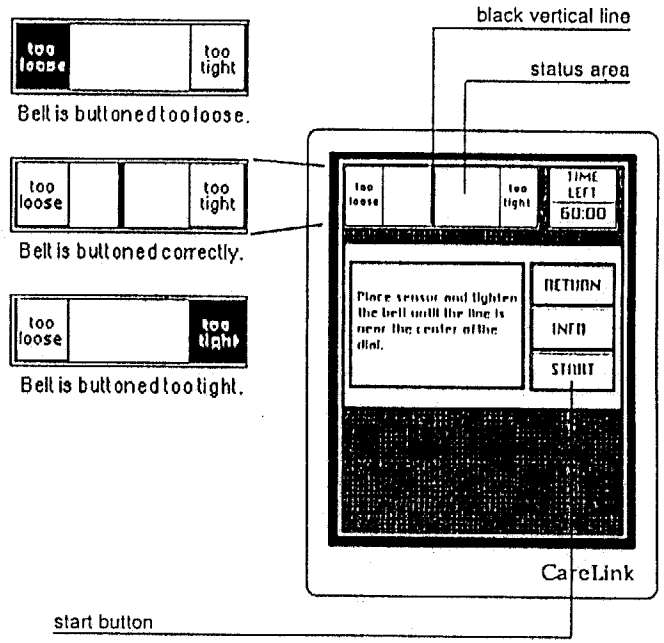
The black vertical line in the status area of the video screen tells you when the toco belt is properly adjusted. The *too loose* box turns black when the elastic belt is too loose. The *too tight* box turns black when the elastic belt is too tight. Adjust the toco belt and monitoring will resume. (Note: see Tab 8 on *Interrupting a Monitoring Session* for more information about pausing while monitoring.)

Steps 5 and 6: Uterine Monitoring Instructions

5. Tighten or loosen the toco belt until the black vertical line is near the middle of the status area at the top of the video screen.

6. Touch START to begin monitoring.

Toco Belt Adjustment Indicators and Screen



Signs and Symptoms Questions

Each time you begin monitoring, you will be asked questions about the signs and symptoms of labor. Always take time to think about each question and then touch the YES or NO button.

When all the questions have been answered, an important message will appear on the video screen, and an OK button will appear. When you have read the message, touch OK.

Steps 7 and 8: Uterine Monitoring Instructions

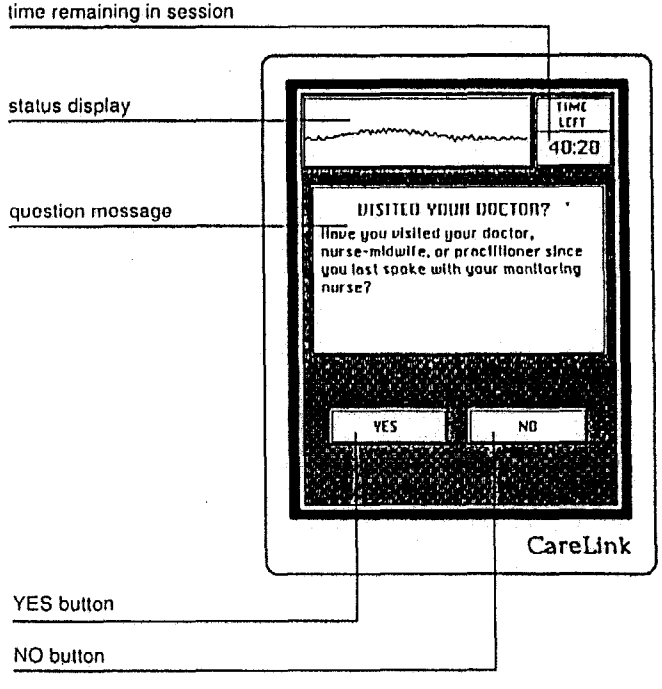
7. Touch YES or NO to answer each question.

8. Read the reminder message after the questions, and touch OK when you have finished.

Note: If you do not understand the message, or have any questions, please call your monitoring center.

Note: To change answers to the signs and symptoms, see Tab 4.

Message screen showing YES and NO buttons



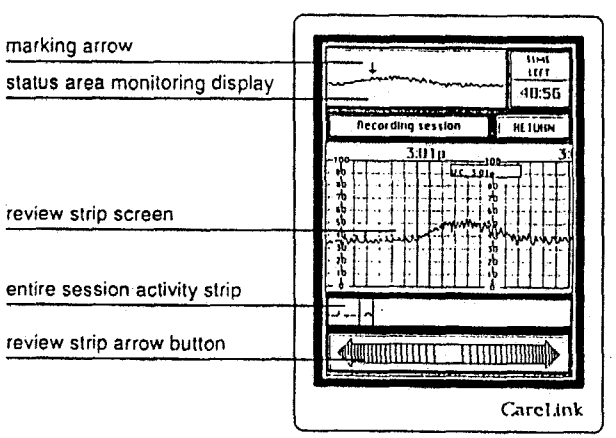
Watching the Monitoring Session

The Status Area Monitoring Display shows the uterine activity as it is happening. It is a compact version of the monitoring information. The Review Strip screen also shows the uterine activity as it is happening, but is larger and easier to view. Use Step 9 if you want to watch your uterine activity on the Review Strip Screen while monitoring, or at a later time.

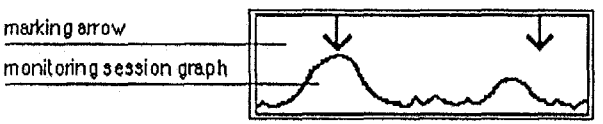
You may be instructed by your monitoring center to make a marking arrow whenever you feel a uterine contraction or some other event.

The Status Area Monitoring Display is touch-sensitive. An arrow will appear when you touch the Status Area Monitoring Display with your finger. This arrow is called a *marking arrow*. You can make a marking arrow as often as every 40 seconds during a monitoring session.

Uterine Activity Monitoring Screen



Closeup of Status Area Monitoring Display



The monitoring session graph looks like hills and valleys which may indicate uterine activity.

Step 9: Uterine Monitoring Instructions

9a. To view the session *as you are monitoring*, touch the **VIEW SESSION** button. Move your finger along the **Review Strip Arrow** at the bottom of the screen to go forward or backward along the strip and to adjust speed. (Note: if you are currently monitoring and have not touched the arrow in the last 30 seconds, the viewpoint will automatically move to show the latest uterine activity as it is being collected.)

9b. Touch the *Status Area Monitoring Display* whenever you feel a uterine contraction to make marking arrows to let your monitoring center know what you are feeling.

9c. To review the session *at a later time*, touch **Options**. Then touch **VIEW SESSION**. Move your finger along the **Review Strip Arrow** to go forward or backward.

Ending and Automatically Sending a Session

When you are approaching the last five minutes of your monitoring session, you must not use the telephone so that the CareFone™ console is free to send your monitoring information to your monitoring center.

At the end of 60 minutes of monitoring, the CareFone program automatically stops monitoring and removes the monitoring display from the status area. You may then remove the toco belt. The CareFone console will send the session to your monitoring center where the information will be reviewed when it arrives.

After sending a monitoring session, stay off the phone for about 30 minutes to keep your line clear for the monitoring center to call you.

Step 10: Uterine Monitoring Instructions

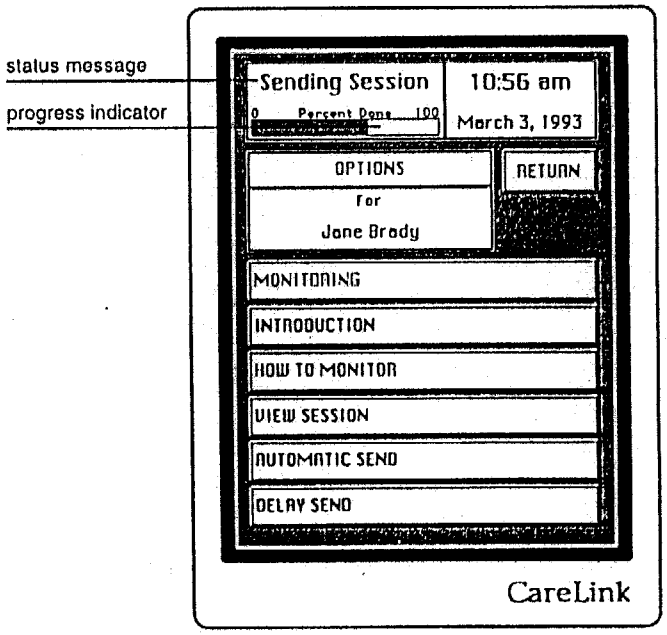
10. End any telephone calls before you reach 5 minutes remaining on the Time Left clock. When the clock runs out, take off the toco belt. You have now completed monitoring. Note: do not attempt to use the telephone while data is being sent to your monitoring center.

Sending a Session

While the CareFone™ console prepares to send the monitoring information, the disk drive makes some humming noises and the status area changes.

During this time the status area shows the percentage of the session that is sent. Note: this display is normal and does not indicate problems.

Telephone screen showing a session sending progress message



Points to Remember

- Push the black reset button whenever you change to a different disk.
- Keep the tocotransducer located on your abdomen as instructed.
- If the video screen says that the toco belt has become too tight or too loose during a monitoring session, readjust the belt and monitoring will resume.
- End phone calls about 5 minutes before the end of your monitoring session. The CareFone™ console cannot send monitoring information while the phone is being used.
- Whenever you have questions, please call your monitoring center.

SUMMARY OF UTERINE ACTIVITY MONITORING INSTRUCTIONS

1. Insert the *Home Uterine Activity Monitoring* diskette into the disk slot opening. Push the reset button. Touch TOUCH TO CONTINUE.
2. Touch Options.
3. Touch MONITORING.
4. Button the toco belt to the tocotransducer and wrap it around your waist.
5. Tighten or loosen the toco belt until the black vertical line is near the middle of the status area at the top of the video screen.
6. Touch START.
7. Answer each question YES or NO.
8. Read the reminder message and touch OK when finished. If you have questions, please call your monitoring center.
9. When you feel uterine activity, touch the Status Area Monitoring Display to make a marking arrow. To watch the session on the Review Strip screen while monitoring, touch VIEW SESSION.
10. After 60 minutes, monitoring will end and you may remove the toco belt. The Status screen will change to say *Sending Session* and the system will automatically send the session to your monitoring center. You have now finished this uterine activity monitoring session.

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Tab 1

GROUNDING INSTRUCTIONS

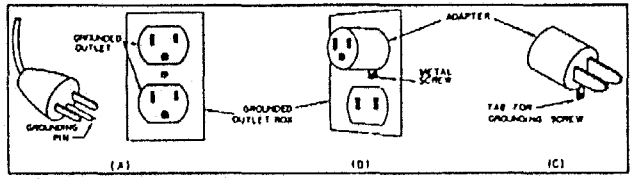
The CareFone HUAM must be grounded. In the event of an electrical short circuit, grounding reduces the risk of electric shock by providing an escape wire for the electric current. The CareFone monitor is equipped with a cord having a grounding wire with a grounding plug. The plug must be plugged into an outlet that is properly installed and grounded.

> DANGER -- Improper use of the grounding plug can result in a risk of electric shock.

Do not attempt to repair or replace the power cord or plug. Call your monitoring center to request a replacement.

Check with a qualified electrician or serviceman if the grounding instructions are not completely understood, or if in doubt as to whether the CareFone™ monitor is properly grounded.

The CareFone HUAM is for use on a nominal 120V AC electrical circuit, and has a grounding plug that looks like the plug illustrated in sketch A. A temporary adapter, which looks like the adapter illustrated in sketches B and C, may be used to connect this plug to a 2-pole receptacle as shown in sketch B if a properly grounded outlet is not available. The temporary adapter should be used only until a properly grounded outlet (sketch A) can be installed by a qualified electrician.



The green colored rigid ear, lug, and the like extending from the adapter must be connected to a permanent ground such as a properly grounded outlet box cover. Whenever the adapter is used, it must be held in place by the screw.

If it is necessary to use an extension cord, use only a 3-wire extension cord that has a 3-blade grounding plug, and a 3-slot receptacle that will accept the plug on the CareFone HUAM. Replace any damaged cord.

Tab 2

UNDERSTANDING THE CAREFONE™ VIDEO SCREEN

The CareFone HUAM is easy to use. You operate it by touching the video screen with one finger. The following pages explain how to use your CareFone video screen.

CareFone Video Screen

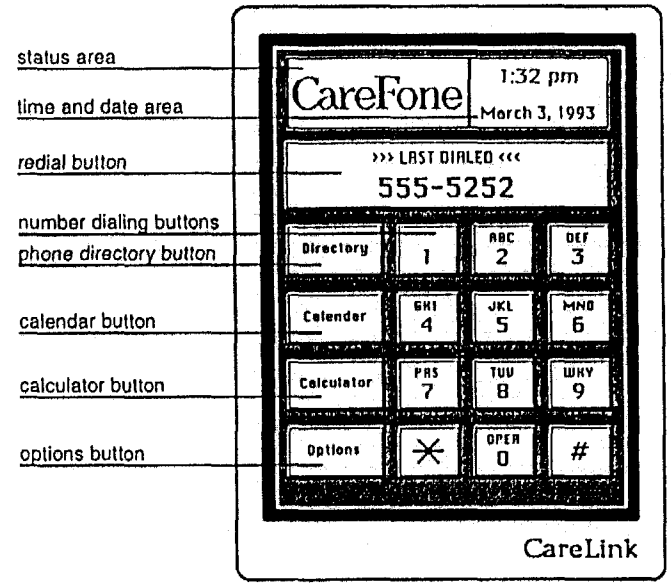
The glass window of the CareFone console is the video screen. This screen is *touch-sensitive*. This means that you tell the CareFone HUAM what you want it to do by touching *special words* on the screen with your finger. These special words have a heavy black outline around them so that they look like push buttons.

RETURN

Choose a word or number button by touching the button on the video screen with one finger. Use the pad of your fingertip -- not the fingernail -- to touch the screen. Wait for the button to turn black and then lift your finger straight away from the video screen. Each time you select a word or number button, the information on the screen will change. If you touch a button you did not want, slide your finger along the glass to the correct button, wait until it turns black, and then lift your finger straight off the video screen.

When you activate your CareFone HUAM, the first screen you will see is the Startup screen. Touch the TOUCH TO CONTINUE button on the Startup screen and you will see the Telephone screen. It looks much like the number pad of a touch-tone telephone.

Telephone screen showing special word and number buttons



Status Area Messages

At the upper left corner of the video screen is the *status area*. This is a message box that tells you what activity the CareFone HUAM is performing at that time. This message changes each time the CareFone™ program begins a new activity. If you have a question about a message you see in the status area, please call your monitoring center. When there is no message, a logo appears in the status area.

Tab 3

VIEWING INFORMATION SCREENS

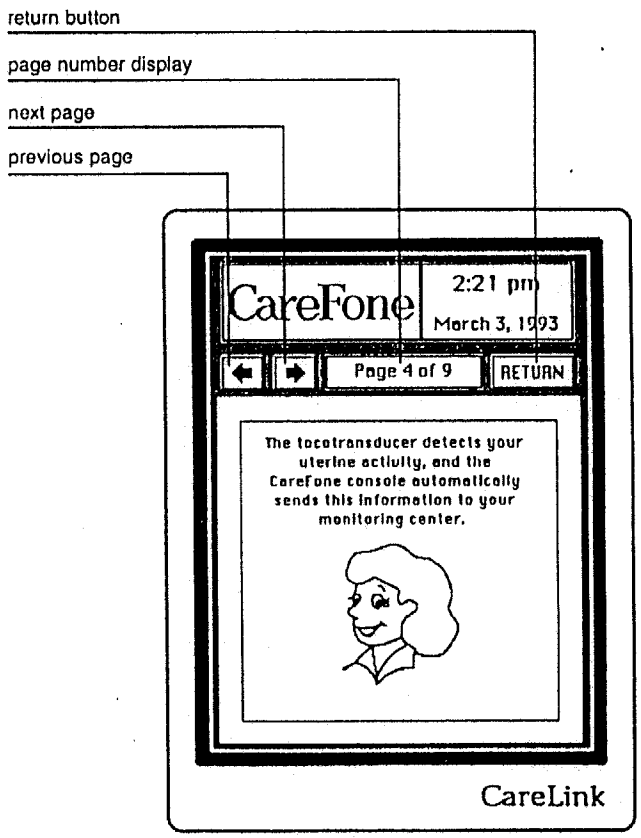
Two series of information screens are available on the CareFone™ console to provide further understanding of the monitoring process. The *Introduction* series explains how monitoring fits into the CareFone system. The *How To Monitor* series contains detailed monitoring instructions.

The Information screens may be viewed at any time, even while monitoring. You may find this information especially helpful by viewing it before beginning the monitoring procedure.

Steps to View Information screens

1. If needed, touch RETURN until you see the Telephone screen.
2. Touch Options.
3. Touch INTRODUCTION or HOW TO MONITOR.
4. Touch the Left or Right arrow to "turn" the page.
5. Touch RETURN to go back to the Options screen before the series ends, if desired.

Sample Information screen



Tab 4

CHANGING ANSWERS TO THE SIGNS AND SYMPTOMS QUESTIONS

When you finish answering the questions about your signs and symptoms and touch the OK button, monitoring will be in process and the Options screen will appear. If you feel dissatisfied with the answers you gave to the questions, you can change them within the first five minutes of a session.

To do this, check that there are more than 55 minutes left on the session timer at the upper right corner of the video screen and then press the END MONITORING button on the Options screen. The video screen will ask if you are sure you want to end the session, so press the YES button. The video screen will then ask if you want to send such a short session to the monitoring center anyway, and you should touch the NO button, to be able to start over and re-do your answers.

These actions bring you to the Options screen with no session in progress. Start the session over again by touching the MONITORING button and the START button and then re-answer the signs and symptoms questions with new answers as desired.

Tab 5

MANUALLY SENDING A SESSION

In special cases, you may have been instructed to use MANUAL SEND. If you have not been instructed to do this, the rest of this page will not apply to you.

If you have been instructed to keep MANUAL SEND in effect, the CareFone™ console will not automatically send the session data to the monitoring center when the session ends. It will need some help from you to make the connection. Your monitoring center will instruct you on how to send the data.

When a monitoring session ends, the video screen will display a reminder for you to dial your monitoring center and start the data transmission. Touch the OK button to acknowledge the reminder and then dial the monitoring center data number using your CareFone console as a telephone.

When the connection is made and you hear a constant tone, press the SEND NOW button. A video screen message will remind you to hang up the phone handset when it is okay to do so. After you hang up, the data will be sent and the CareFone monitor will automatically break the connection when it is finished. No further attention will be required from you.
Note: do not attempt to make telephone calls until the upper left corner of the video screen no longer shows the *Sending Session* message.

Tab 6

STATUS AREA MESSAGES

Problems Sending a Session

If the CareFone™ console has a problem sending a session, the status area will show one of the messages listed below. Should any of these messages continue for 30 minutes or more, please call your monitoring center.

Status Area Message	*Explanation or Possible Causes*	*Suggested Remedy*
Waiting to Send Attempt Canceled	The DELAY SEND button was pressed.	The display shows the time remaining before the next automatic attempt. To send immediately instead, touch the SEND NOW button.
Waiting to Send Phone In Use	Your phone is ringing, the phone handset is off the hook, or the Directory Change screen is active.	Hang up the phone handset. Complete any directory changes in the Change screen if applicable.
Waiting to Send No Dial Tone	The system cannot dial the monitoring center. Other phones in the house could be off the hook.	Be sure the phone cord is plugged into the wall jack. Unplug the phone cord from the CareFone™ console and then plug it back in. Check the other phones in the house — they may be in use or off-hook.
Waiting to Send Busy	The monitoring center phone is busy.	The CareFone console will try again after a short period. Call your monitoring center if you see the message for 30 minutes or more. (Note: pressing SEND NOW will cause the CareFone console to make another send attempt right away, rather than waiting for its next automatic attempt.)
Waiting to Send Modem Not Ready	There may be a problem with the sending components in the CareFone console.	
Waiting to Send No Answer	The monitoring center computer is not answering the line, or the call did not go through to the monitoring center.	
Waiting to Send No Handshake or Waiting to Send Transmission Errors	Noisy telephone line, call waiting tone present, transmission interrupted while sending, or someone picked up an extension.	

Tab 7

SENDING MONITORING SESSIONS IN SPECIAL SITUATIONS

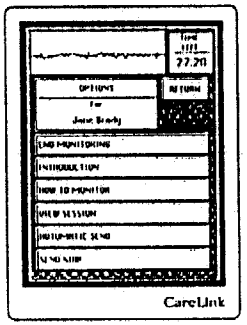
In special situations, you may be asked by your monitoring center to send your monitoring session *before* the 60-minute session is over, or you may be asked to resend your last session.

END MONITORING Button

If you are asked to send the session that you are monitoring now, even though it is not finished, use the END MONITORING button.

Steps to Send Now

1. Hang up the phone handset if not on the receiver.
2. Touch RETURN until you see the Options screen, if needed.
3. Unless instructed otherwise, be sure the next-to-last button is set to AUTOMATIC SEND. Touch MANUAL SEND to change it to AUTOMATIC SEND, if necessary.



4. Touch END MONITORING.
5. Touch YES to end the session.
6. Remove the toco belt at this time, or later.
7. Touch YES to send the session (asked only if the session is less than 5 minutes old).

The CareFone™ console will end the session and send it to your monitoring center. The status area will show that the CareFone console is sending the monitoring information.

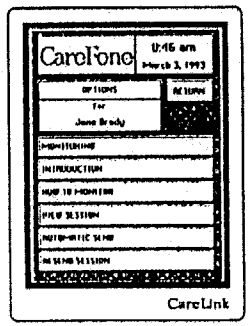
RESEND SESSION Button

Use the RESEND SESSION button to send the last session another time. Use it only when you are asked to resend a session. If accidentally pressed, touch CANCEL SEND to stop the send attempt.

Steps to Resend

1. Touch RETURN until you see the Telephone screen, if needed.
2. Touch Options.
3. Touch RESEND SESSION.

   Note: You cannot resend a session when the phone handset is off the hook.



Tab 8

INTERRUPTING A MONITORING SESSION

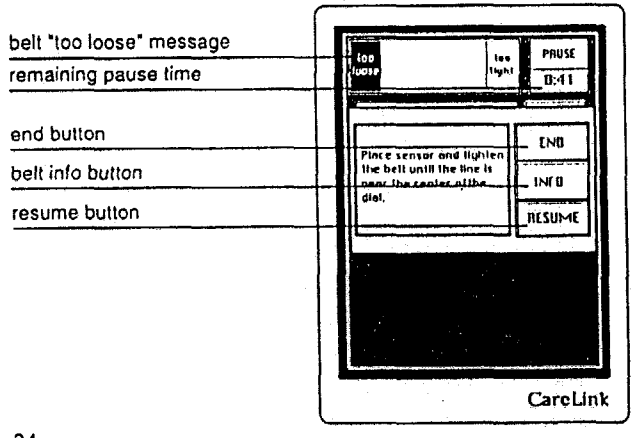
As you monitor your uterine activity, you may need to end, interrupt, or resume a session. Three features of the CareFone™ device that help you do this are the Pause Clock and the END and RESUME buttons.

When you interrupt a session, the Pause Clock keeps track of the time while you are not monitoring. The END and RESUME buttons allow you to stop or restart a session. The clock and the buttons appear when you loosen or take off the elastic belt during a monitoring session.

Note: Touch the INFO button if you want to review how to adjust the toco belt.

The following pages explain more about how to use the Pause Clock and the END and RESUME buttons.

Interrupted Session screen showing the Pause Clock and END, INFO, and RESUME buttons



Pausing During a Session

Interrupt a session by loosening or removing your toco belt. The Pause Clock tracks the time left for 10 minutes.

The CareFone™ console beeps every minute as a reminder to come back and tell it what you want it to do. The CareFone console starts to alarm continuously during the last two minutes.

After pausing during a session, your choices are to stop the session or resume monitoring. The END button stops the session, and readjusting the toco belt restarts the session.

If you do not touch the END button or readjust the belt, the CareFone program will automatically end your session after ten minutes of pause and send it to your monitoring center.

Caution: Avoid using pauses more than *three* times in any one session or you might be required to remonitor. Call your monitoring center if you have any questions.

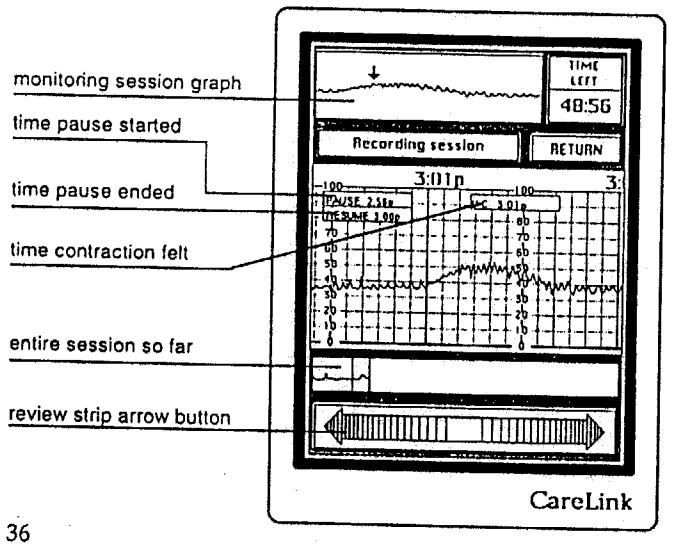
Ending a Short Session

The END button appears when you loosen or take off the toco belt during a monitoring session. Touching END ends the session early and sends the session data to your monitoring center. Touching END MONITORING while monitoring also ends the session and sends it.

Resuming a Session

If you have not touched the END or END MONITORING buttons, readjusting the toco belt restarts the monitoring session where you left off. The CareFone™ program records the pause time and the resume time on the monitoring session graph.

Uterine Activity Monitoring screen showing pause, resume, and felt contraction times



Steps to Pause and Resume, or to Pause and End

1. Remove the toco belt. The video screen shows the Pause Clock with the time left.
2. Touch END if you need to end the session.
3. If there is time remaining on the Pause Clock and you want to resume the session, place the toco belt around your waist. Adjust the belt until the black vertical line is in the middle of the status area.
4. The session automatically resumes.
5. Continue monitoring until the session is complete.

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Tab 9

USING THE CAREFONE™ CONSOLE TELEPHONE

The CareFone console is also an easy-to-use telephone. It works just like a touch-tone telephone.

You can use it to make calls whether or not you are monitoring. However, you cannot make calls when the CareFone console is in the process of sending a session because the CareFone device uses the telephone line to send the monitoring data to your monitoring center.

When dialing, the CareFone console automatically selects whether to use pulse (rotary) or touch-tone dialing for your line. If it is using pulse dialing and you need tone dialing after you get into an automatic switchboard, touch the star (*) or pound sign (#) button to switch to tone for the rest of that call. When you hang up, the CareFone programming resets back to pulse mode for the next call.

Dialing the individual digits in pulse mode takes longer than tone dialing. Do not be concerned if you notice pulse dialing lagging behind your button touches.

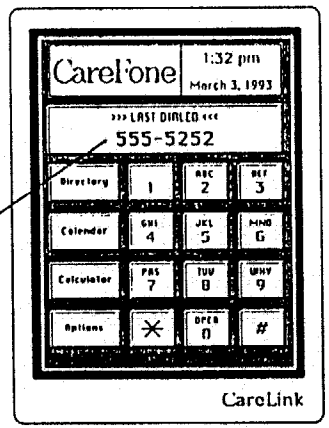
Touch Dialing

One method of dialing is called *touch dialing* because you touch the numbers on the video screen. Use the Telephone screen for touch dialing phone calls. The numbers will flash black as the phone number is dialed. (Note: no dialing occurs unless the phone handset is off of the receiver.)

Steps to Use Touch Dialing

1. Pick up the phone handset.
2. Touch the numbers of the phone number you want to dial.

   Note: To redial, touch the telephone number that appears on the "LAST DIALED" message button.



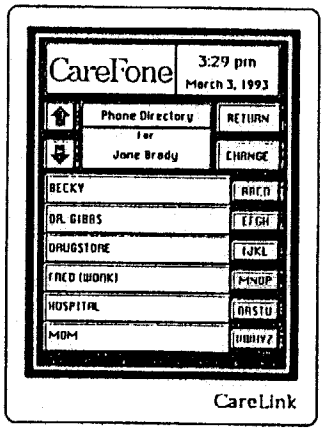
Directory Dialing

The CareFone™ Directory allows you to create a list of names and telephone numbers. (Your monitoring center telephone number and certain other important numbers may already be programmed in the Directory for you.)

Touch the Up and Down arrows or alphabet index buttons to move through the alphabetical Directory. listings. The CareFone device dials the telephone number when you touch the name that you want to call. This makes it easy to call people or places that are listed in the Directory.

Steps to Use Directory Dialing

1. Touch the RETURN button until you see the Telephone screen, if needed.
2. Pick up the phone handset.
3. Touch Directory on the Telephone screen.
4. Use the Up and Down arrows or alphabet index buttons on the Directory screen to find the person or place you want to call.
5. Touch the name or place that you want to call.



Tab 10

USING THE CAREFONE PERSONAL PHONE BOOK

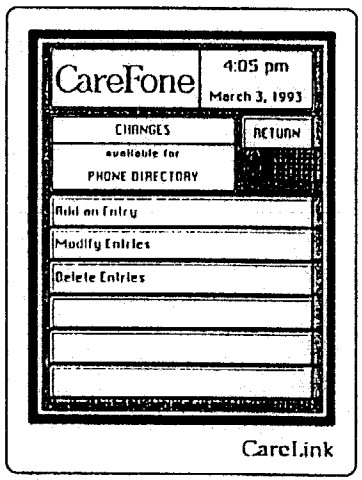
The CareFone™ console can be used as a personal phone book by adding the names of relatives, friends, or businesses to your CareFone Directory. You can also remove or change the names and the telephone numbers in the Directory.

Making Changes in the Directory

The types of changes that you make in the Directory are shown on the Change screen of the Directory. They are:

- Add an Entry (add a name and phone number)
- Modify Entries (change names or phone numbers)
- Delete Entries (remove names and phone numbers)

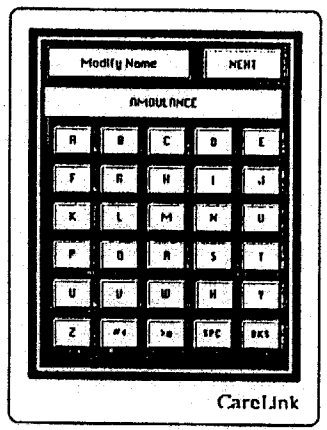
Change Screen for the Directory



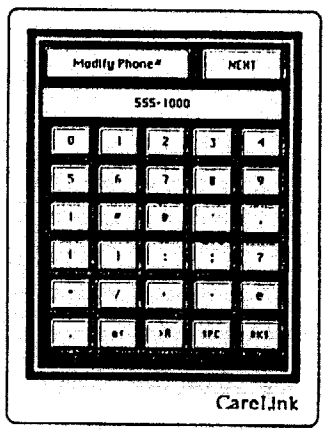
Adding a Name and Telephone Number

Any name and telephone number can be added to the Directory. The Directory shows names shorter than 20 letters (including the spaces). To type a space, touch the SPC button. For very long names, you may want to use abbreviations. To type small letters, touch the a< or >a buttons. To type numbers, touch the #< or ># buttons. To return to typing capital letters, use the A< or >A buttons.

Type in the telephone number the same way you would dial it. For example, if you need to dial a "1" before the area code, type the number 1. You do not need to use spaces, "( )", or hyphens around the area code, but adding such marks will not interfere with the dialing, and may make the numbers more readable. If you type a name or number incorrectly, you can "erase" it by backspacing character by character. To do this, touch the BKS button. You may put dashes in the number by touching the hyphen button, located above the SPC (space) button.



CAPITAL LETTERS SCREEN



NUMBERS SCREEN

Special dialing characters

Certain non-numeric characters can be used in Directory dialing strings for special purposes. For instance, the alphabetic characters, in either capital or lower case, can be used as they would on a touch-tone phone to dial equivalent numbers for commercial lines that encourage you to call them by dialing easy-to-remember words instead of numbers.

Certain alphabetic characters can be embedded in a dialing string to force the dialing to a specific mode. Where a "Z" is inserted in the string, the dialing mode is forced to tone mode from that point on. A "z" does the same thing, but only until the next reboot of the CareFone™. Where a "Q" is used, the dialing mode from then on is forced to pulse (rotary), and a "q" has the same effect, but only until reboot. As already described, "*" or "#" will force the dialing to tone mode just for the current call.

Each comma inserted in the dialing string will cause a two-second pause in the dialing, to provide a wait for secondary dial tones to be acquired. Any number of commas may be used consecutively to obtain whatever length pause is needed.

Dialing String Example: The following string might be used to dial a long distance number using a telephone line that only allows pulse dialing. After dialing, it would wait eight seconds for the call to go through to an automated phone system, and then use tone dialing to dial the desired extension.

1-619-555-4422 , , , , * 204

Steps to Add a Name and Phone Number to the Directory

1. Touch Directory on the Telephone screen.
2. Touch CHANGE on the Directory screen. (Note: this button will not be available while monitoring is in progress.)
3. Touch Add an Entry.

4a. Touch each letter to spell out the name that you want to add. The CareFone™ video screen can only show the all-capital-letters screen or the all-small-letters screen at one time.

4b. To switch from small letters to capital letters touch the >A button.

4c. To switch from capital letters to small letters touch the >a button.

5. Touch NEXT.
6. Touch each number or character of the telephone number that you want to add.
7. Touch RETURN until you reach the Directory screen.
8. Check the name and number of the new entry by touching the name in the Directory. If you do not see the name, use the Up and Down arrows to find it.

Modifying a Name or Phone Number in the Directory

Any name and telephone number that is already in the Directory can be changed.

Steps to Modify a Name and Phone Number

1. Touch **Directory** on the Telephone screen.
2. Touch **CHANGE** on the Directory screen. (Note: this button will not be available while monitoring is in progress.)
3. Touch **Modify Entries.**
4. Touch the name you want to modify.
5. Touch the BKS (backspace) button to remove one letter at a time.
6. Touch each letter to spell out the name that you want to add.
7. Touch NEXT.
8. Touch the BKS button to remove one number at a time.
9. Touch each number of the telephone number that you want to add.
10. Touch NEXT.
11. Touch RETURN until you reach the Directory screen.
12. Check the name and the number by touching the name in the Directory. If you do not see the name, use the Up and Down arrows to find it.

Deleting (Removing) a Name and Phone Number from the Directory

If you want to remove a name and telephone number from the Directory, use the Delete Entries button.

If you accidentally delete the wrong name, you can use **Add an Entry** to put the name back on the list.

Steps to Delete a Name and Phone Number

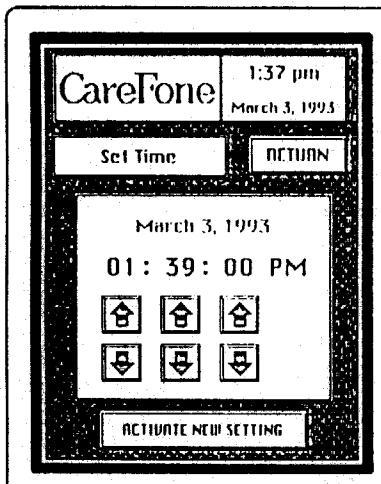
1. Touch **Directory** on the Telephone screen.
2. Touch **CHANGE** on the Directory screen. (Note: this button will not be available while monitoring is in progress.)
3. Touch **Delete Entries.**
4. Touch the name you want to remove.
5. Touch YES if the selection is correct.
6. Touch RETURN until you reach the Directory screen and check that the name has been removed.

Tab 11

SETTING THE CAREFONE™ DATE AND TIME

The date and time in the status area at the top of the CareFone video screen normally will be set for you. If you want to change these settings you may do so, but you should let your monitoring center know if you do make any substantial changes.

In the Time Settings screen, there are up and down arrow buttons aligned below the units of time that they change. Touch an up button to increase a time or date unit — touch a down button to decrease one. If you keep a steady touch on an arrow button, the units will continue to change until you remove your finger.



CLOCK SETTING SCREEN

When you have the setting that you want, touch the ACTIVATE NEW SETTING button at the moment that you want it to be effective. You can redo this several times if desired. When you are satisfied with the settings, exit by touching the RETURN button.

Steps to Set the Date and Time

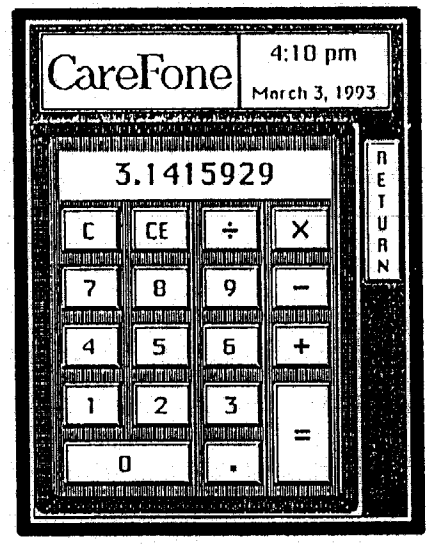
1. Touch Calendar on the Telephone screen.
2. Touch **Set Clock** on the Calendar Settings screen. (Note: this button will not be available while monitoring is in progress.)
3. Touch the up and down arrow buttons until you have the settings you desire.
4. Touch the ACTIVATE NEW SETTING button at the moment you want your setting to take effect.
5. Touch RETURN to exit.

Tab 12

USING THE CAREFONE™ CALCULATOR

An additional feature of the CareFone monitor is the provision of a four-function floating-point calculator. Operation of the calculator is identical to the manner in which common desk and pocket calculators are used.

The display has a maximum of eight digits, and, if the result of a calculation cannot be expressed within that format, the answer screen will read, "Error: Too large". Attempts to divide by zero will have the same result. As on other calculators, this condition can be cleared by touching the C (Clear) button.



CALCULATOR SCREEN

The CE (Clear Entry) button is used to clear a keyed-in number when you want to re-enter the number without losing stored results.

Steps to Use the Calculator

1. Touch **Calculator** on the Telephone screen.
2. Touch the calculator buttons in the same manner as for a desk or pocket calculator.
3. Touch RETURN to exit.

Tab 13

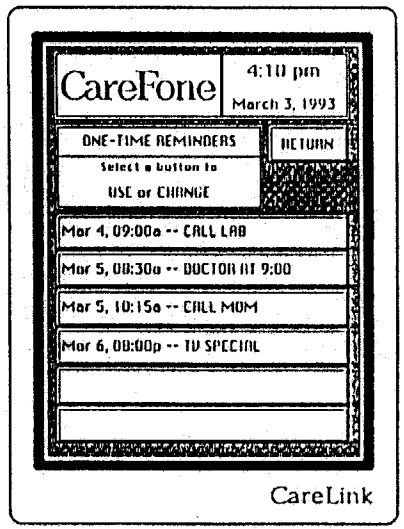
USING THE CAREFONE™ REMINDERS FUNCTIONS

You can program the CareFone console to display pop-up reminders for your appointments and everyday activities. An alarm will sound and a message will appear whenever you want to remember something you should do. The following pages explain how to use these features.

POP-UP REMINDER SCREEN

Adding to the CareFone™ One-time Reminders

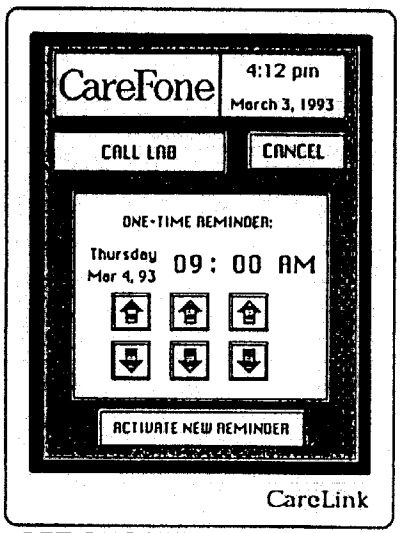
The One-Time Reminders provide a way for you to set up reminders for appointments, phone calls, and other one-time events that you do not want to forget. The reminder panel will appear on the CareFone video screen on the date and time that you specify, with the message that you specify, and will make an alarm noise until you touch the OK button to acknowledge it.



ONE-TIME REMINDERS

After one-time notices come due and are shown and acknowledged, their entries are automatically removed from the list, making room for new ones. Up to six of these one-time reminders can be pending in the CareFone at any time.

When you key in your "message" for the Reminder screen to display, use a word or words that will identify the event at that time, such as "DOCTOR'S APPOINTMENT" or "CALL MOTHER". Naturally, for something like an appointment, you should set the alerting time for when you need to start getting ready, rather than the actual time of the appointment. The actual time of the appointment may best be included in the message portion of the entry.



SET ONE-TIME REMINDERS

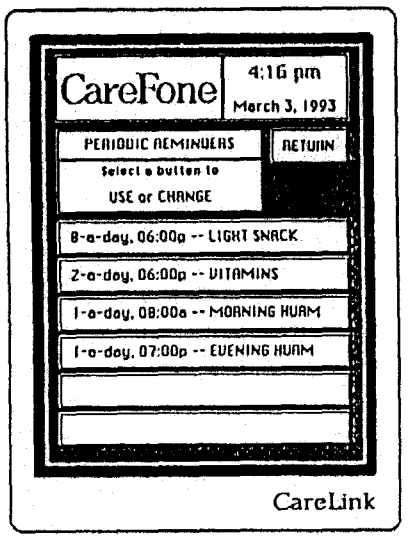
Steps to Create a One-Time Reminder Entry

1. Touch Calendar on the Telephone screen.
2. Touch Set One-Time Reminders on the Calendar Settings screen.
3. Touch any empty (blank) button on the One-Time Reminders screen.
4. Use the Text Entry screen to key in a phrase that will identify the reminder for you when it comes on-screen. When complete, touch CONTINUE.
5. Touch the arrow buttons until you have the date and time setting that you desire for the Reminder screen.
6. Touch the ACTIVATE NEW REMINDER button when you are finished. One of the buttons on the One-Time Reminders screen will now show the time and text of your new reminder setting. (If you press the CANCEL button instead of the ACTIVATE NEW REMINDER button, the entry will be discarded.)
7. Touch RETURN to exit.

Note: for information on how to change or remove a one-time entry, please see the section *Changing or Removing Reminders.*

Adding to the CareFone™ Periodic Reminders

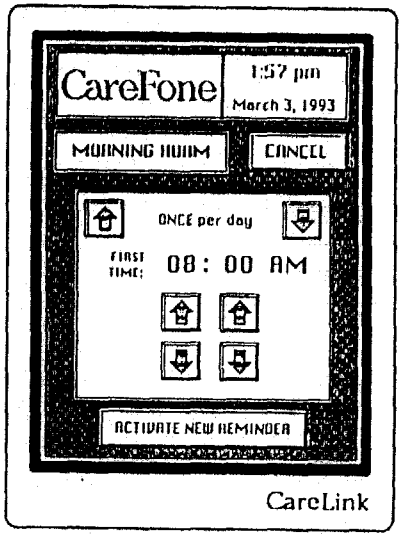
The Periodic Reminders feature provides reminders that you can use to help remember such repeating activities as exercising, drinking water, taking vitamins and, of course, doing your daily monitoring sessions.



PERIODIC REMINDERS

For each reminder entry, you can choose how often you want it to remind you, from once a day to twenty-four times a day. The reminder panel will appear on the video screen with the frequency that you specify, with the message that you specify, and will make an alarm noise until you touch the video screen to acknowledge it.

After periodic reminder notices come due and are shown and acknowledged, their entries stay on the list, ready to come up again the next time they are due. They will continue cycling until you deliberately remove them from the list when no longer wanted. Up to six of these periodic reminder notices can be pending in the CareFone™ periodic reminders list at any time.



SET PERIODIC REMINDERS

When you key in your "message" for the Reminder screen to display, use a word or words that will identify the event, such as "VITAMINS" or "MONITORING".

Steps to Create a Periodic Reminder Entry

1. Touch **Calendar** on the Telephone screen.
2. Touch **Set Periodic Reminders** on the Calendar Settings screen.
3. Touch any empty (**blank**) button on the Periodic Reminders screen.
4. Use the Text Entry screen to key in a phrase that will identify the reminder for you when it comes on-screen. When complete, touch **CONTINUE**.
5. Touch the upper arrow buttons until you have the number of times per day, or the hours between the times, that you desire for the reminders.
6. Touch the lower arrow buttons until you have the starting time setting that you desire for the beginning of the reminders cycle.
7. Touch the **ACTIVATE NEW REMINDER** button when you are finished. One of the buttons on the Periodic Reminders screen will now show the frequency and text of your new reminder setting. (If you press the **CANCEL** button instead of the **ACTIVATE NEW REMINDER** button, the entry will be discarded.)
8. Touch **RETURN** to exit.

Changing or Removing Reminders

To change a pending reminder, select the entry you want to alter by touching its button in the One-Time Reminders or Periodic Reminders screen, and then alter the text or effective date and time as desired. Always end with the **ACTIVATE NEW REMINDER** button when you are satisfied with the settings. If you decide not to alter the entry after all, touch the **CANCEL** button in the Time-Setting screen to leave the entry unchanged.

To cancel a one-time reminder entry before it comes due, or to remove a periodic reminder entry, select its button in the One-Time Reminders or Periodic Reminders screen and then use the **BKS** (backspace) button to erase its entire text string. When you touch **CONTINUE** with an empty text string, the entry will be removed from the list.

Tab 14

CLEANING INSTRUCTIONS

- Cleaning the CareFone console and phone handset with a soft, damp (not wet) cloth. Use a mild dish soap for hard-to-clean areas. Do not use aerosol sprays, solvents, or abrasives that might damage the finish.
- Clean the video screen with a household glass cleaner lightly sprayed onto a clean cloth or a paper towel. Do not spray any liquid directly onto the case and damage the device.

Tab 15

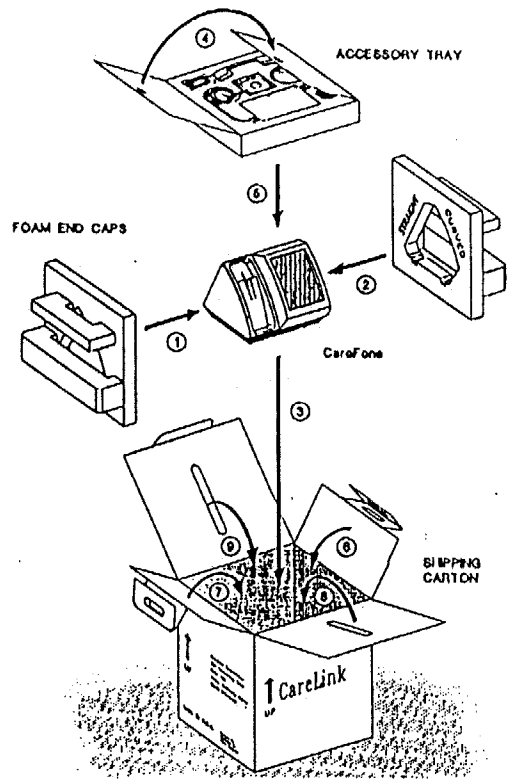
INFORMATION ON THE CARE OF YOUR DISKETTE

- Don't expose diskette to temperatures outside of 50" to 140" F. .
- Don't slide the silver tab back and forth to prevent exposure of the magnetic media.
- Keep diskette away from magnets.

Tab 16

REPACKING THE CAREFONE™ HUAM SHIPPING CARTON

Your CareFone HUAM came packaged in a special box. To return the equipment, please follow the diagram below. If you have any questions, please telephone your monitoring center.



Repacking the CareFone™ Monitor Accessory Tray

Photo of Accessory Tray

* Additional accessories supplied from CareCenter

Tab 17

CAREFONE™ TROUBLESHOOTING GUIDE

Symptom	Likely Causes	Suggested Remedies	Pge
• "Waiting to Send" for more than 30 minutes.	• Cause identified in status area of video screen.	• See pages 30-31.	30
• No dial tone in phone handset.	• Poor phone cord connection • Coiled handset cord not correctly plugged in.	• Check phone line for dial tone with another phone or extension. If dial tone is present, check that one end of phone cord is plugged securely into back of CareFone console and other end is plugged into telephone wall jack. • Unplug handset cord from handset and console. Wipe plugs on handset cord with a dry cloth and plug handset cord back in. Be sure hookswitch is not stuck down.	9
• Video screen is black but console makes noise when reset button is pressed.	• Foreign object on video screen or near screen edge. • Video screen dirty or dusty. • HUAM diskette not working properly.	• Remove object. • Clean screen and screen edges with soft cloth. • Replace diskette in diskette drive with spare HUAM diskette and press reset button*	9
• Video screen is black and console does not make noise when reset button is pressed.	• No power to CareFone console. • No diskette in diskette drive.	• Make sure CareFone cable is plugged into live power outlet and that the cord connections are tight. • Insert HUAM diskette and press reset button.	9 9
• Diskette drive makes continuous whirring noises.	• HUAM diskette not working properly.	• Replace diskette in diskette drive with spare HUAM diskette and press reset button*	9
• Belt indicator reads "too tight" or "too loose".	• Toco belt not properly adjusted.	• Adjust toco belt until black vertical line reappears on belt-indicator screen (do not over-tighten).	21
• Video screen does not respond to touches.	• Too much light shining on video screen. • Foreign object touching video screen.	• Redirect or eliminate light source or change CareFone console angle or location. • Remove object.	
• CareFone program restarts on its own.	• Loose AC power cord connection. • Inconsistent power source (interference from lightning, brown-outs, momentary black-outs).	• Be sure AC power cord is plugged into a live power outlet and that the cord connections are tight. • Wait until interference subsides. Press reset button and start monitoring again if needed.	9
• MONITORING button is gray and does not respond to touches.	• Session recorded on HUAM diskette has not been sent. • HUAM diskette not working properly.	• Press SEND NOW button. • Replace diskette in diskette drive with spare HUAM diskette and press reset button*	9
• Console appears damaged.	• Shipping damage or other physical abuse.	• Unplug AC power cord from power and contact your monitoring center.	

* Contact your monitoring center for a replacement HUAM diskette.

If problems persist, call your monitoring center.

The monitoring center staff will attempt to solve the problem over the telephone. If the problem cannot be remedied, the CareFone monitor will be replaced. Your monitoring center will instruct you on what you need to do.

IMPORTANT PERSONAL INFORMATION

Your monitoring nurse is:

_____

Your monitoring center telephone number is:

_____

Your physician's name is:

_____

Section II

Instructions for the

Indy Nurse Station System

Instructions for the Indy Nurse Station System

I. Introduction to the Indy Nurse Station

II. Main Screen (Nurse Station Window)

A. Session Buttons

1. Session buttons box
2. Receiving sessions
3. Printing sessions
4. Viewing sessions
5. Storing sessions
6. Viewing sessions which have been stored
7. Printing sessions which have been stored
8. Deleting sessions in the session List
9. Modifying a session

B. Options Buttons

10. Pat Info
    a. Entering a new patient information
    b. Modifying patient information
    c. Finding patient information
    d. Deleting patient file and sessions
11. Assign CCs
12. Restarting the computer

I. Introduction

These instructions are a guide to help the user operate the Indy Nurse Station System. The System has been created to make patient care more efficient.

The Indy nurse station program will allow the nurses to receive, view, print, and store patient sessions. The system is designed to be easy to use and allows the monitoring nurse to process patient sessions.

The most notable advantage of the Indy system is its ability to distribute sessions to particular computer stations. Each station will be assigned a certain group of patients. These patients are identified by social security numbers and CareCenter code (CC code). The Indy will direct the session by CC code, from the file server, to the computer which is assigned that code. All CC codes will need to be assigned to a specific computer. The CareCenter will make this assignment daily for the designation of computers. The flexibility of this system allows any CC coded session to be viewed from any computer.

IMPORTANT: The modem next to your machine may be receiving sessions from CareCenters which are not assigned to your station. This means that the modem may receive information and you may hear it go off, but you may not see a session come up in the session list on your computer.

Please read the following instructions before using the Indy system. Refer to them as needed, or if you have trouble working the system. If you have any questions or comments, please contact CareLink for help.

II. Main Window (Nurse Station Window)

When the computer is turned on or restarted it automatically will bring up applications which are needed to process the patient sessions. This process is invisible to the user (nurse). These applications allow the computer to receive, view, print, store, and send sessions. The screen on the computer monitor will look like Figure II-1 if the applications are automatically turned on correctly. When you start your shift, look at the monitor screen and make sure it looks like figure II-1.

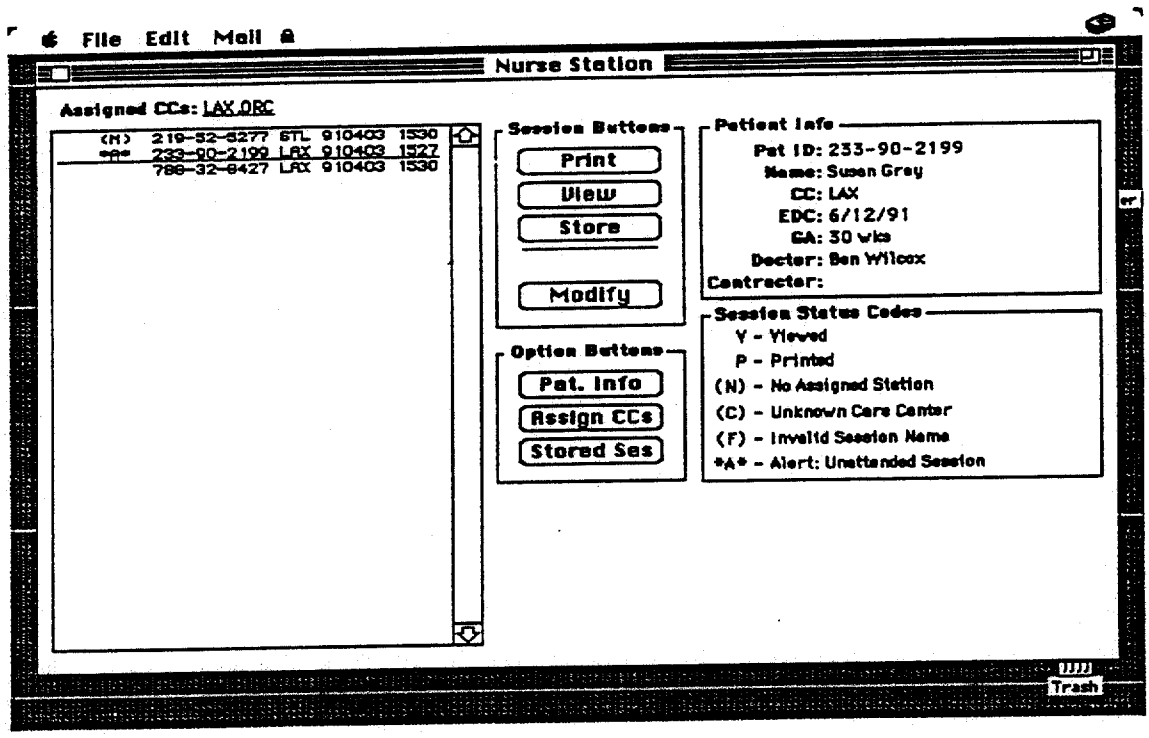


Figure II-1
Nurse Station Window

Note:
The mouse cursor will look like a hand icon with a pointing forefinger. The active spot of this icon is the tip of the finger. To select an item, point the tip of the finger and click the mouse on the item. Be careful to only click the mouse once when you make your selection.

Before operating the Indy computer system, become familiar with the screen's components. Figure II-2 is a picture of the Nurse Station Window.

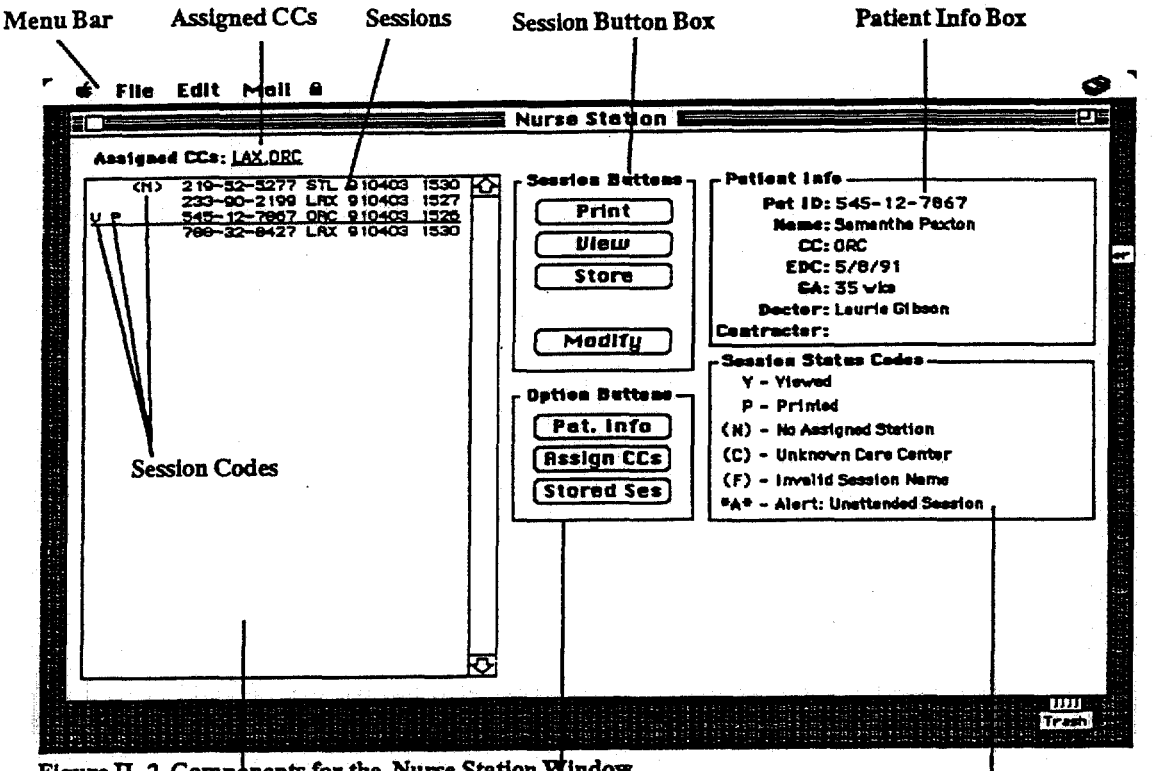


Figure II -2 Components for the Nurse Station Window

Nurse Station Window

Session List Box - This box contains incoming sessions. Each line in the session list contains the session's status, patient's social security number or patient ID number, CareCenter, and session date and time. Session status codes indicate whether a session has been viewed or printed, if there is an assigned nurse station for this session, if the CareCenter for this session is valid, if the nurse staion recognizes the session name, or if the session has been unattended.

Assigned CCs - This area shows the currently assigned care centers for this nurse station. Any sessions which come in for the assigned CareCenters will appear in the Session List of the assigned computer(s). More than one computer may be assigned to a CareCenter.

Menu Bar -At the top of the screen is the menu bar. The menu bar lists\commands available to the user. When a command is selected, it will display a list of commands. The rest of the computer screen will freeze as long as the command is selected.

Session Status Codes - Session Status Codes describe the processes which have occured for that session. These codes indicate whether a session has been viewed or printed, if there is an assigned nurse station for this session, if the CareCenter for this session is valid, if the nurse station recognizes the session name, or if the session has been unattended. The codes are:

V	The session has been viewed by a nurse station
P	The session has been printed by the nurse station
(N)	The session has no assigned nurse station
(C)	The session's CareCenter is not in the Master CareCenter List
(F)	The session's name cannot be recognized. The session name must be exactly 27 characters long and in the proper format. (A valid session format is ###-##-#### aaa yymmdd hhmm; example; 123-45-6789 ORC 910512 2031)
A	**The session has been unattended for at least 15 minutes. Unattended means the session has not been viewed or printed.**

All sessions should be viewed within 15 minutes of receipt. The *A* is an important alert and should not be ignored.

Patient Info Box - Patient information is displayed when a session is selected. It consists of Patient ID, Patient's Name, CareCenter, EDC, GA, Doctor's Name, and Contractor (other care giver or service).

Session Button Box - These buttons are used to perform certain functions with the currently selected session. These functions are;

Print - selected session will print out at the assigned printer.
View - shows the selected session on the computer screen.
Store - stores or files the session in a patient folder.
Delete - deletes the session **permanently** from the system.
* **Do Not Delete Sessions** unless you are sure it is a duplicate or a test session.
Modify - modifies the session name. This should only be used if he session's CareCenter is not in the master CareCenter code list or the name configuration is wrong.

Option Button Box - These buttons are for other features of the nurse station.

Pat. Info - opens the patient information window where information is added, modified, and deleted.
Assign CCs - allows the user to choose which CareCenter's sessions will appear in the session list box.
Stored Ses - allows access to the file where sessions are stored.

1. Session Button Box

The session buttons are used to perform certain functions with the currently selected session. These functions allow the user to process the sessions. The functions are Print, View, Store, Delete, and Modify.

If a session is selected in the Session List Box the Session Buttons will darken and this will allow the user to activate them (see Figure 1-1). Otherwise, the buttons will appear grey and the buttons will not respond when the user clicks on them (see Figure 1-2).

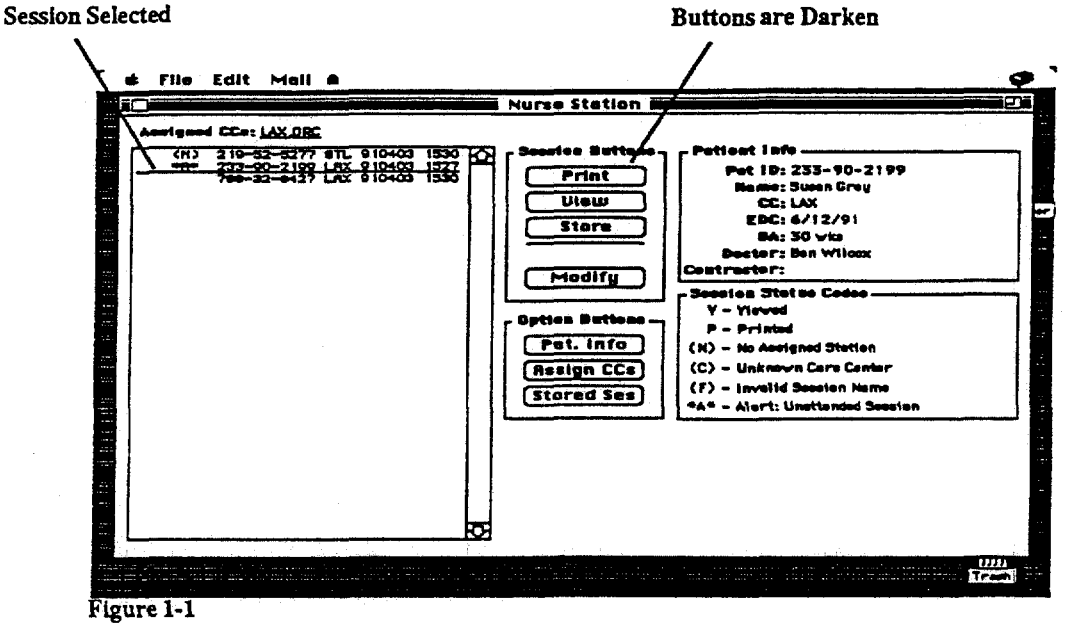


Figure 1-1
Session Buttons Darken

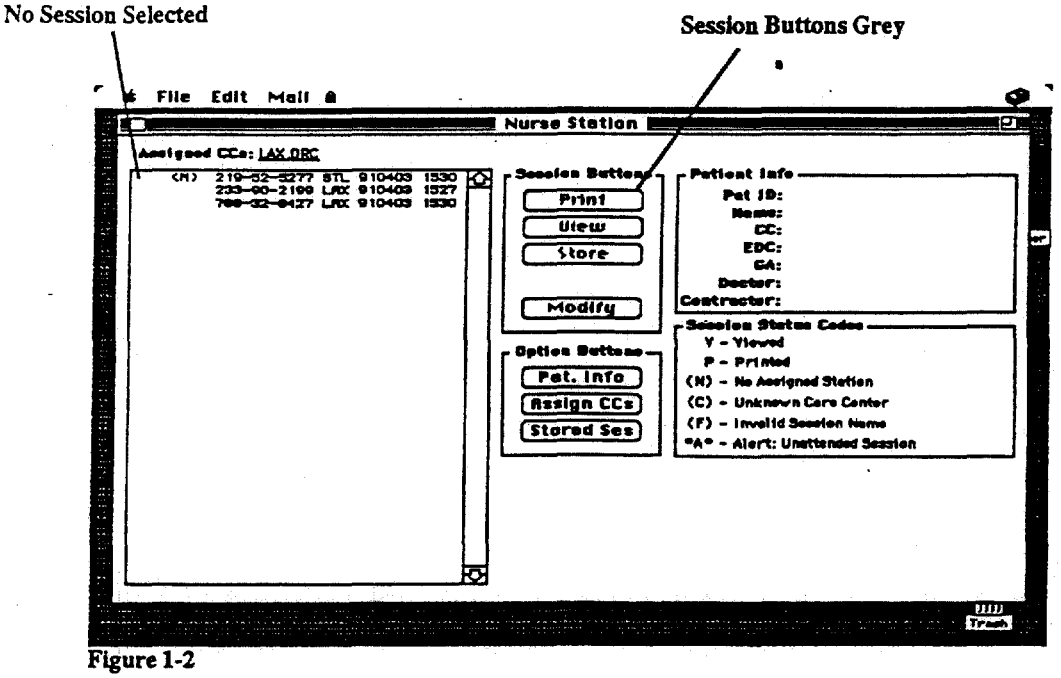


Figure 1-2
Session Buttons Grey

2. Receiving Sessions

The CareFone Access application turns on automatically when the computer is turned on or restarted. This application receives the sessions and places them in the window so the nurse can process the sessions. The Social Security # which is programmed into the patient's HUAM disk will show up in the Session List Box on the left side of the window (see Figure 2-1).

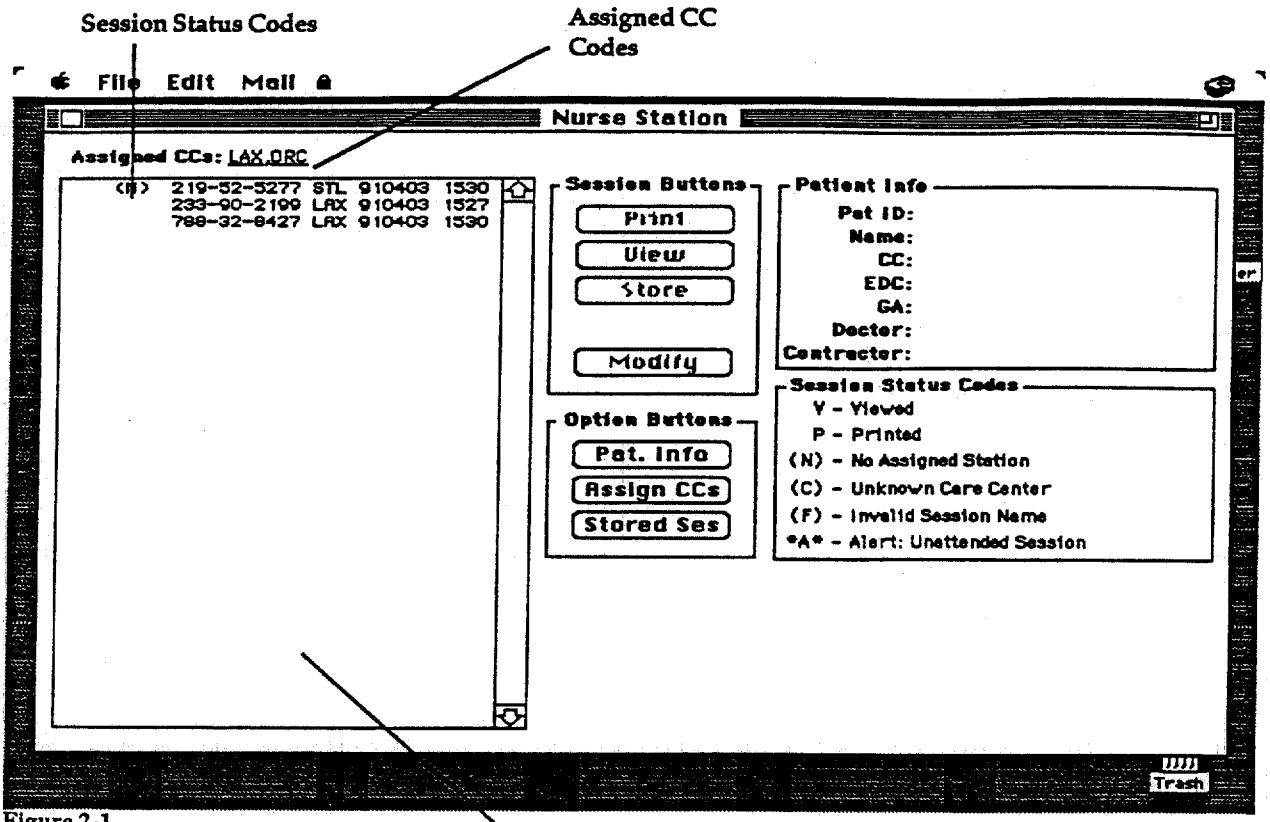


Figure 2-1

When a session is received, the file server (central computer) will distribute the session to the assigned computer. The social security number will appear in the session list window.

If a session comes in without an assigned CC code it will appear on all computers. This is to assure that it is processed.

The sessions will appear in the order of time received. The newest session received will come up on top. As the sessions are processed session status codes will appear to the left of the session.

If the session has been unattended for greater than 15 minutes it will appear on top with the "Alert" status code *A*. The session will appear on all computers.

3. Printing Sessions

The "Print" button (see Figure 3-1) will send the selected session to the printer. To set the current printer, please see the Macintosh computer manual. Once the session has been sent to be printed, the letter P is put into the session's status area. The P status will be seen on all nurse stations which have access to this session. All sessions must be printed before storing them. To print sessions follow these steps:

3.1 Select the desired session in the session list box.

3.2 Move hand cursor to the print button in the sessions buttons box.

3.3 Click the mouse once. The session selected will print out at the designated printer*.

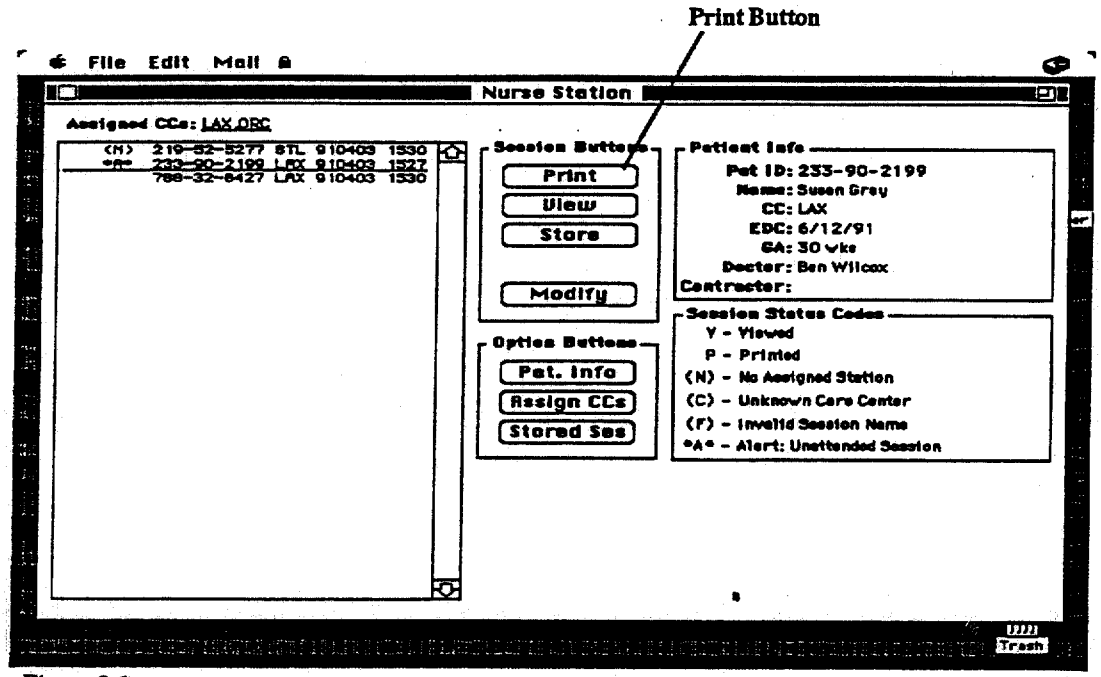


Figure 3-1
Print Button

***All sessions must be printed before storing. Make sure the session prints out and that you have the session, before storing it. The status code "P" does not guarantee that the session will print successfully. (e.g. printer may be out of paper, etc)**

4. Viewing Sessions

The nurse will use the computer to help triage sessions as they are received. To process the session the nurse will use the buttons in the Session Button Box. (see Figure 4-1)

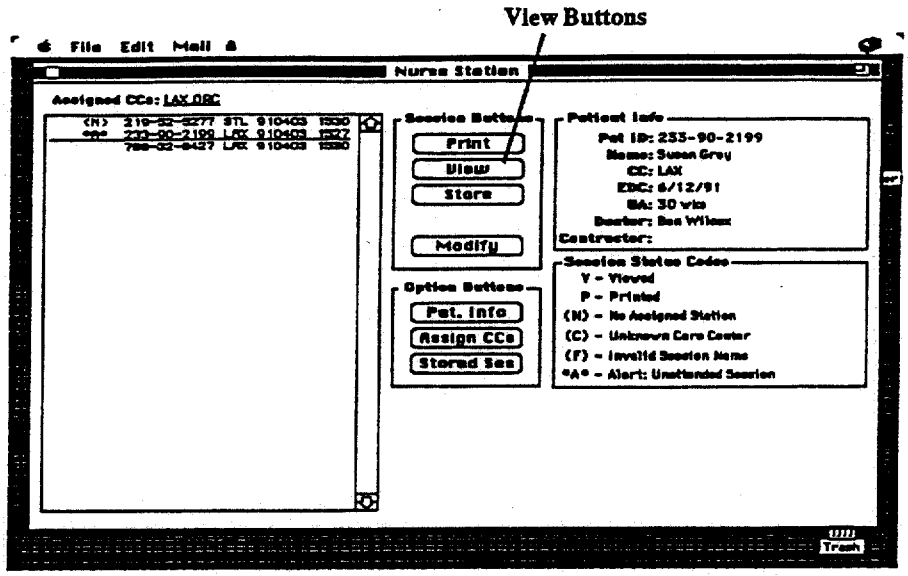


Figure 4 - 1
View Button

To view session before or while they are printing, follow these steps;

4.1 Select the session which is to be viewed from the session list box. To select, move the hand cursor to the session number and click once. When the session is selected a line will show up under it.

4.2 Move the hand cursor to the Session Buttons box and point to the button labeled "View".

4.3 Click the mouse once. The session will then appear on the computer screen.

4.3 To return to the Nurse Station Window click the mouse on the close box in the left hand corner of the window.

5. Storing Sessions

The "Store" button will remove sessions from the session list and store them in the patient's folder (see figure 5-1). The computer will create the folder automatically for each patient's ID. A session can be retrieved later from the patient's folder for viewing or printing. The session cannot be stored if it has not been printed. Likewise, if the session's CareCenter is not in the master list (C status Code) or the session's name is not recognized (F status code) then the session cannot be stored.

If the session is a duplicate and has been previously stored, a message appears asking if the old session should be replaced. If the "Yes" button is pressed, the session will be replaced. If the "No" button or the Return Key (on the keyboard) is pressed, the session will not be stored and will stay in the Session List. In this case, you may want to Delete the session.

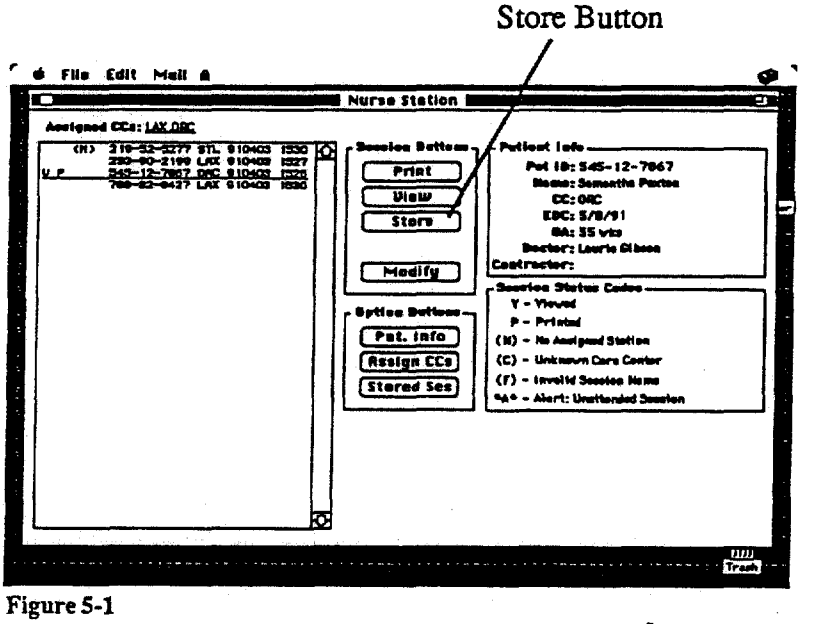


Figure 5-1
Storing Session Button

After printing follow these steps to store the sessions;

5.1 Select the desired session in the session list box.

5.2 Move the cursor to the Store button in the session button box.

5.3 Click the mouse once. The session will disappear from the session list box and automatically file into a folder in stored session.

Caution:
Make sure you have the printed session before storing. Some sessions may not print even though you have followed the above steps and the "P" code shows up next to the session.

6. Viewing sessions which have been stored

Sessions may be viewed after they have been stored. To access them the user must go into the "Stored Ses" window. (see Figure 6-1)

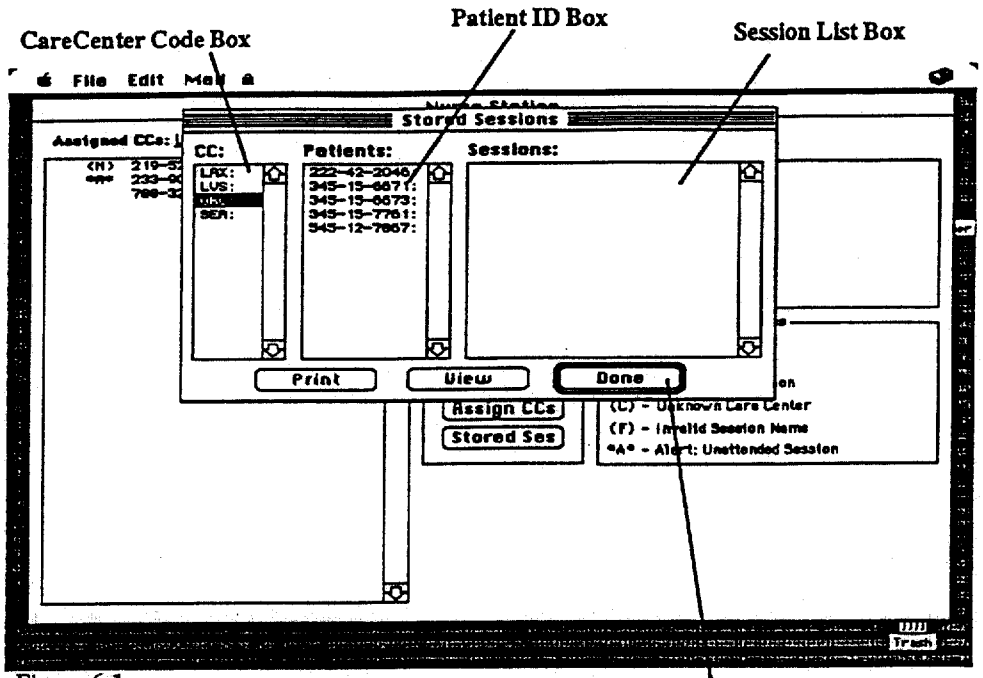


Figure 6-1
Stored Ses Window

To view sessions already stored follow these steps:

6.1 Click the mouse once on the "Stored Ses" button in the Option Button box on the Main Screen.

6.2 Select the desired "CC" code and click the mouse once. A list of Patients ID number(s) for that CareCenter Code will appear in the Patients box.

6.3 Select the ID# desired and click once. A list of sessions will appear in the Sessions box, if the patient has sessions in their folder.

6.4 Select the desired session in the session list box and click the mouse once on the session.

6.5 Click the mouse once on the" View" button.

6.6 After viewing, click once on the close box of the view window. To return to the nurse station screen click once on the "Done" button.

7. Printing Sessions which have been stored.

Sessions may be printed after they have been stored. To access them the user must go into the "Stored Ses" window. (see Figure 7-1)

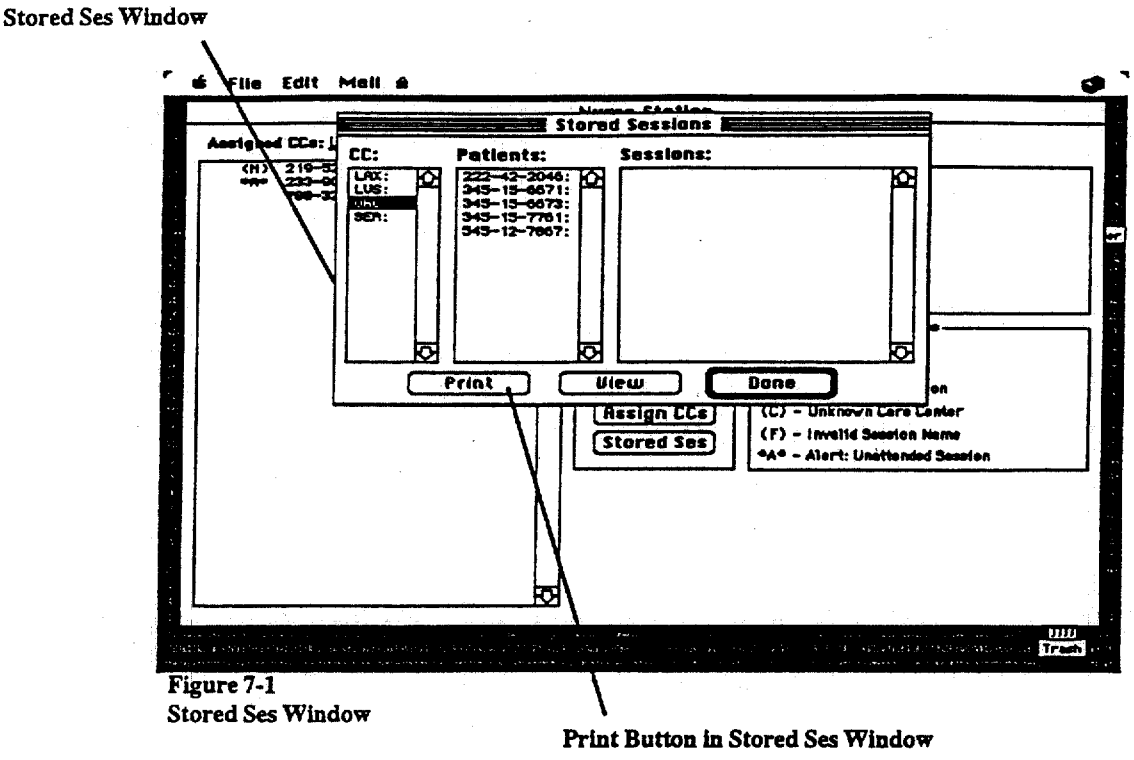


Figure 7-1
Stored Ses Window

To print sessions already stored follow these steps;

7.1 Click the mouse once on the "Stored Ses" button in the Options Button Box.

7.2 Select the "CC" code which is desired and click the mouse once. A list of Patients ID number(s) for that CareCenter Code will appear in the Patients box.

7.3 Select the ID # desired and click once. A list of sessions will appear in the Session Box.

7.4 Select the desired session and click the mouse once on the session.

7.5 Click the mouse once on the "Print" button. The session will automatically print.

7.6 After printing click once on the "Done button" to return to the nurse station main window.

8. Deleting Sessions in the session list

You may wish to delete test sessions or session which have been sent more than once by the CareFone. **DO NOT DELETE ANY SESSION until you are sure it is a duplicate of an already processed, test, or undesired session.** Deleting the session removes it permanently from the system.

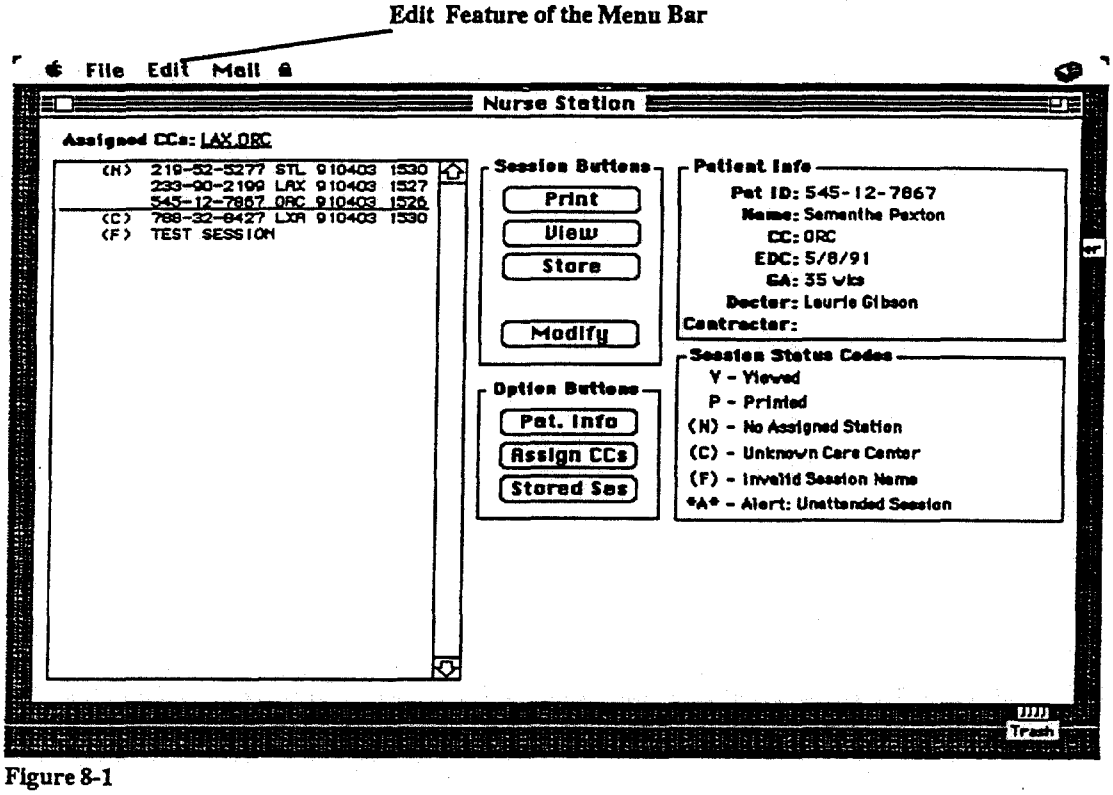


Figure 8-1
Delete Button on the Nurse Station Window

To delete sessions from the session list follow these instructions;

8.1 Select the session to be deleted from the session list box.

8.2 Click and press the mouse on the "edit" feature of the menu bar.

8.3 Scroll down to the "delete session" command and release the mouse.

8.4 An alert box will appear and ask if you are sure you want to delete the session. If you are sure you want to **permanently** delete the session click the "Yes" button. The session will disappear from the session list box.

Once a session is deleted it can not be retrieved.

9. Modifying a session

This system requires the session information which is received from the Care-Fone to have a valid format. (See page 4 for format) If the session is received and does not have a valid format the session title will need to be modified in order to process it. The Modify Button in the Session Button Box allows the user to modify the selected session. This should only be used if the session's CareCenter is not in the Master Care-Center list (status code C) or the session's name is not recognized (status code F).

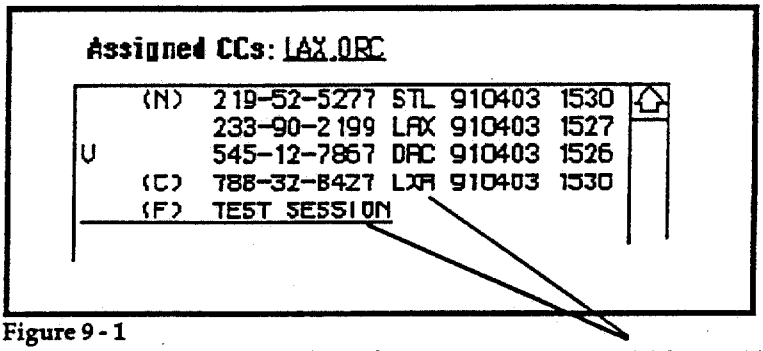


Figure 9 - 1
Session List Box with C and F codes

To modify session name follow these steps:

9.1 Select the desired session in the Session List Box.

9.2 Move the cursor and click the mouse once on the "Modify" button in the Session Button Box.

9.3 A message window will appear saying "This session appears to be OK. Are you sure you want to modify it. YES NO" Click on the "YES" if you are sure you want to modify the session name.

9.4 A message window will appear with the information of the selected session from the Session List Box.

9.5 Move the cursor and click on the portion of the invalid session name. Backspace to remove and type in correct name.

9.6 Click " OK". The session name will automatically change in the Session List Box.

B. Option Buttons

The Option Buttons are functions to other features of the nurse station. These functions are Patient Info, Assign CareCenters, and Stored Sessions.

10. Pat Info

The "Pat Info" button opens the Patient Information Window. This is where patient information is added, modified, and deleted. (See Figure 10 - 1)

The Indy system links the information in "Pat Info" to the appropriate session. The ID number formatted on the patient's disk is linked to the ID number in Pat Info. When the session is received the system connects the information in Pat Info with the session. This information prints out on the top of the session if the numbers match exactly.

It does not matter which computer the Pat Info is entered into. All information is located in the central computer and can be accessed from any computer.

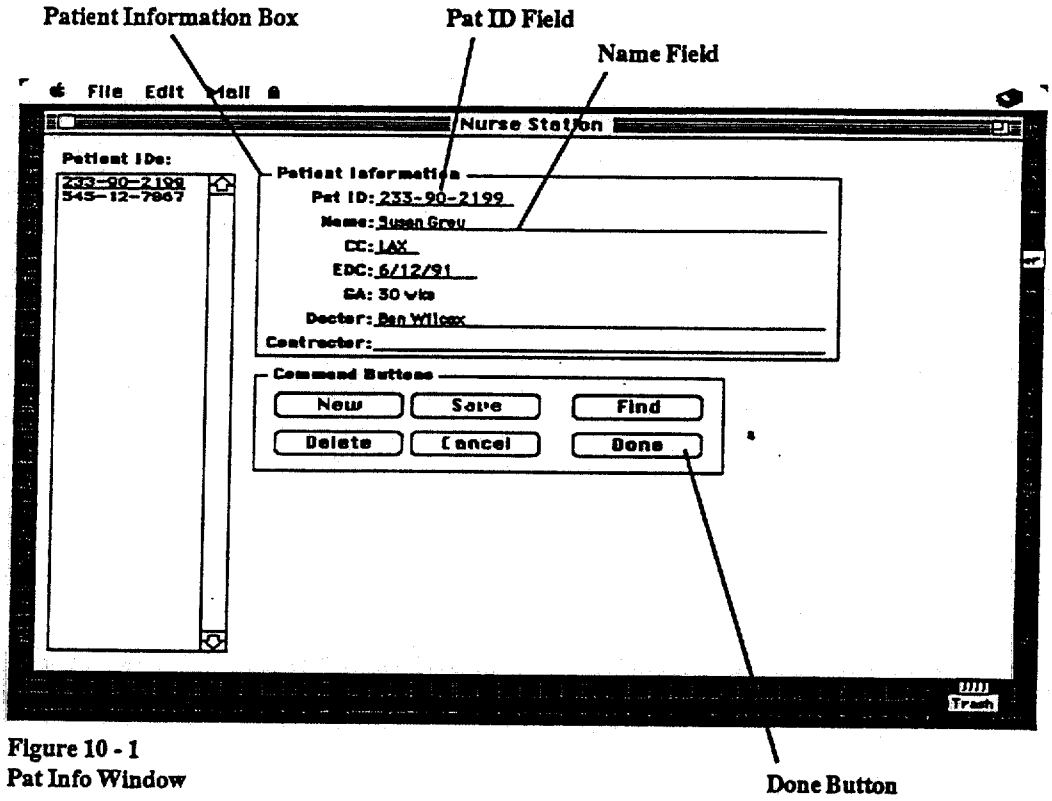


Figure 10 - 1
Pat Info Window

If a session is not selected, the Patient Information Window will be ready to add a new patient. If a session is selected, but there is no existing patient information for the patient, the Pat ID will be filled automatically and the cursor placed at the "Name Field". If the session is selected and the patient information exists for that patient, the patient record will appear in the "Patient Information" window.

10.a Entering new patients into the system ("New" button)

To entering New Patient's Information into "Pat Info" follow these steps:

10.a-1 Click the mouse of "Pat Info" in the Options Button Box. The Pat Info Window will appear on the screen.

10.a-2 Click the mouse on the "New" button. A blank Patient Information Box will appear with the cursor blinking in the "Pat ID" field.

10.a-3 Type in the Patient's ID number using the valid ID format (see page 4 for the valid format). Press the return key or click the mouse on the "Name" field. The cursor will blink in the name field.

10.a-4 Type in the patient's name (e.g. Mary Dow). It will appear on the top of the session exactly how you enter it in this field. Press the return key or click the mouse on the "CC" field.

10.a-5 Type in the desired CC code. Be sure to use the correct assigned code. Press the return key or click the mouse on the" EDC" field.

10.a-6 Type in the EDC using the correct format. (e.g. 01/23/91 or 02-23-91) The GA will calculate and appear automatically if the EDC has been entered in correctly.

The user can not enter into the GA field it will calculate automatically.

10.a-7 Press the return key or click the mouse on the "Doctor" field. Enter in the Doctor's name.

10.a-8 Press the return key or click the mouse on the "Contractor" field. This field is for the name of any other provider which may be handling patient care. (e.g. OptionCare, PharmaThera, etc)

10.a-9 Check all information to assure it is correct. Click on the "Done" button, when you are finished. A message window will appear and ask the user if the record should be saved first. Click "YES" if you want the information saved. If "NO" is clicked the information will be deleted.

The Patient's information must be entered into the system before the patient is setup on the CareFone. If there is no information at the top of the session, when it is received, it will usually mean the information on the patient's disk does not match the information in Pat Info. This must be corrected before the session can be processed. If the Session ID or CareCenter Code is wrong then use the "Modify" function of the Session Buttons. (see page 14 for instructions on modifying a session)

10.b Modifying Patient Information

If the patient information should change or need to be corrected, use these steps to modify the "Pat Info":

10.b-1 Click on the desired session name in the Session List Box which is to be modified. A line will appear under the session name.

10.b-2 Click on the "Pat Info" button on the Nurse Station Window (Main Screen). This will bring up the Pat Info Window. (see page 15, Figure 10 - 1)

10.b-2 The "Pat ID" of the selected session will appear in the "Pat ID" field. If the ID name format is valid and information has been previously enter, the patient information will appear in the fields. If the ID name format is invalid or if no information has been entered, the fields will remain blank.

10.b-3 Click the mouse on the field which is to be modified. Backspace to erase the present information if needed. Type in the correct or new information.

10.b-4 Click on the"Done" button when all changes have been made. The screen will return to the nurse station window.

10.c Finding Patient Information

To locate a Patient's file in Patient Information follow these steps:

10.c-1 Click the mouse on the "Pat Info" button on the Nurse Station Main Window.

10.c-2 Click the mouse on the "Find" button in the Command Button Box of the Pat Info Window. A message window will appear and ask for the desired ID number.

10.c-3 Type in the desired ID number. If the ID number matches a previously entered ID the information will appear in the window. If the information does not match a previously entered file a message window will appear and say "Sorry, patient not found.

If no record is found, check to make sure you have entered the information correctly.

10.d Deleting patient file and sessions

Patients who are off service may be removed from the computers storage space once all patient care has been completed. To remove patient information from the computer you must access "Pat. Info" (see figure 9-1) The user will use this window to delete the patient information and all sessions from the computer. To delete patient information and all session follow these instructions;

10.d-1 Click the mouse once on the "Pat. Info" button in the option button box. This will bring up the Pat Info Window.

10.d-2 Click on the "Find" button in the Command Button Box. A message window will appear and ask you to type in the desired patient ID.

10.d-3 Type in the Pat. ID #. Make sure to use correct format. This will select the patient ID in the Patient ID List. The user may also select a paient by scrolling the patient ID list down and clicking on the desired patient's ID.

10.d-4 The Patient information will appear in the "Patient Info" window.

10.d-5 Click on the Delete Button.

10.d-6 A message window will appear. Read the message and select the response which is appropriate.

Do Not Delete patient records unless you are sure they are to be removed permanently from the system.

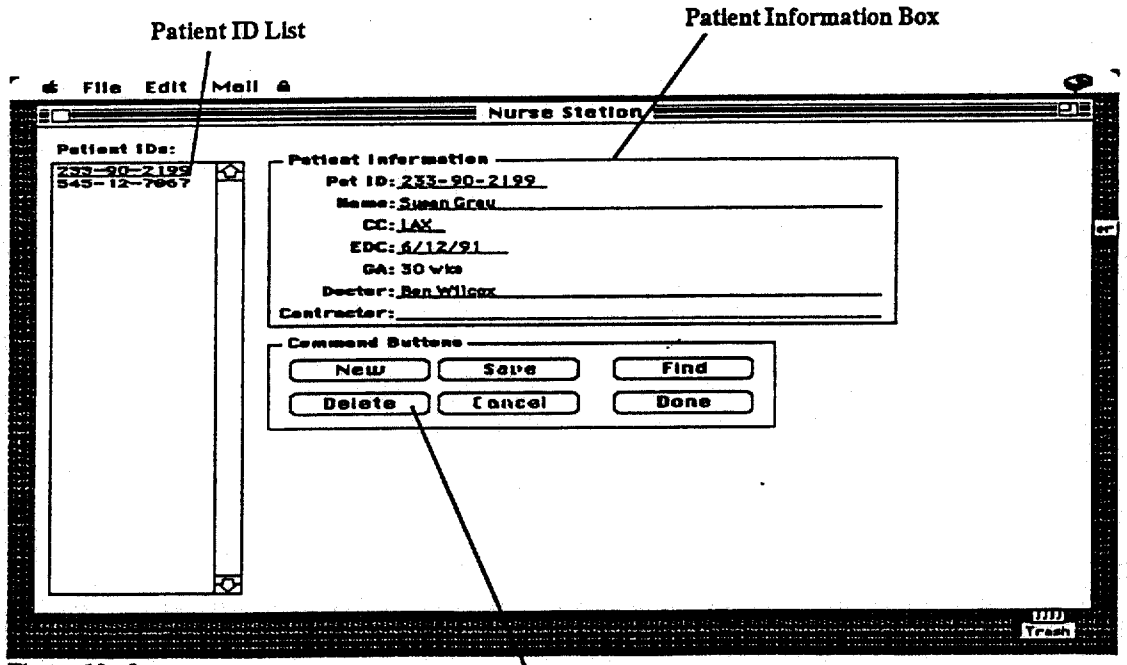


Figure 10 - 2
Pat. Info Window

11. Assigning CCs to the computer

Each computer will be assigned CareCenters. This will route all sessions with the CC code to the computer(s) which have selected the same code. (e.g. If the user selects the CC code ORC for computer 5, all sessions labeled with the ORC will route to the computer 5) Note; CCs code may be selected by more than one computer.

To assign CCs to the computer follow these steps:

11.1 Click the mouse on the "Assign CCs" button in the Option Button Box. The AssingCCs window will appear. It lists all the CareCenters.

11.2 To select the desired CC or CCs click the mouse once on the CC code listed in the Assigned CCs list. A check mark will appear to the left of the code.

11.3 To deselect the CC, click the mouse on the desired CC code once. The check mark will disappear and the CC will no longer be selected.

11.4 To return to the Nurse Station Main Window click the mouse on the "Done" button.

The CCs selected will list in the "Assigned CCs:" field.

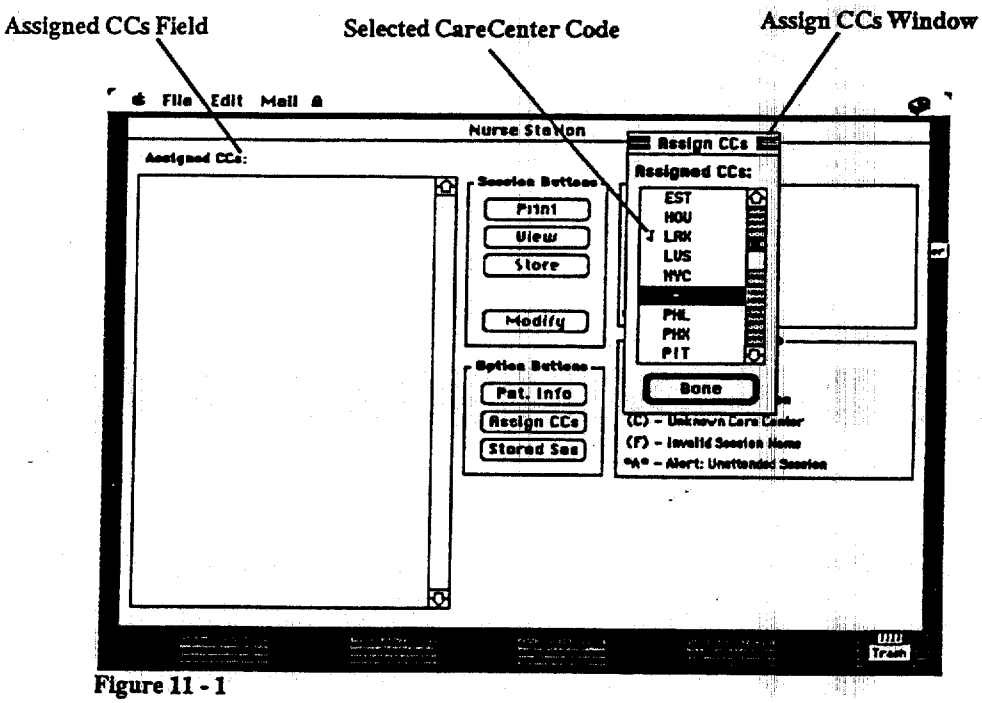


Figure 11 - 1
Assign CCs Window

12. Restarting the Computer

The Monitoring computers do not need to be restarted unless problems arise. If you are having to restart the computers for them to operate correctly, please notify technical support.

If you do need to restart the computer, follow these steps:

12.1 Click and press (hold down on the mouse button) the mouse on File in the menu bar. A list of options will appear under the file menu. It will list Administration, Restart, and Shut Down. See figure 12-1.

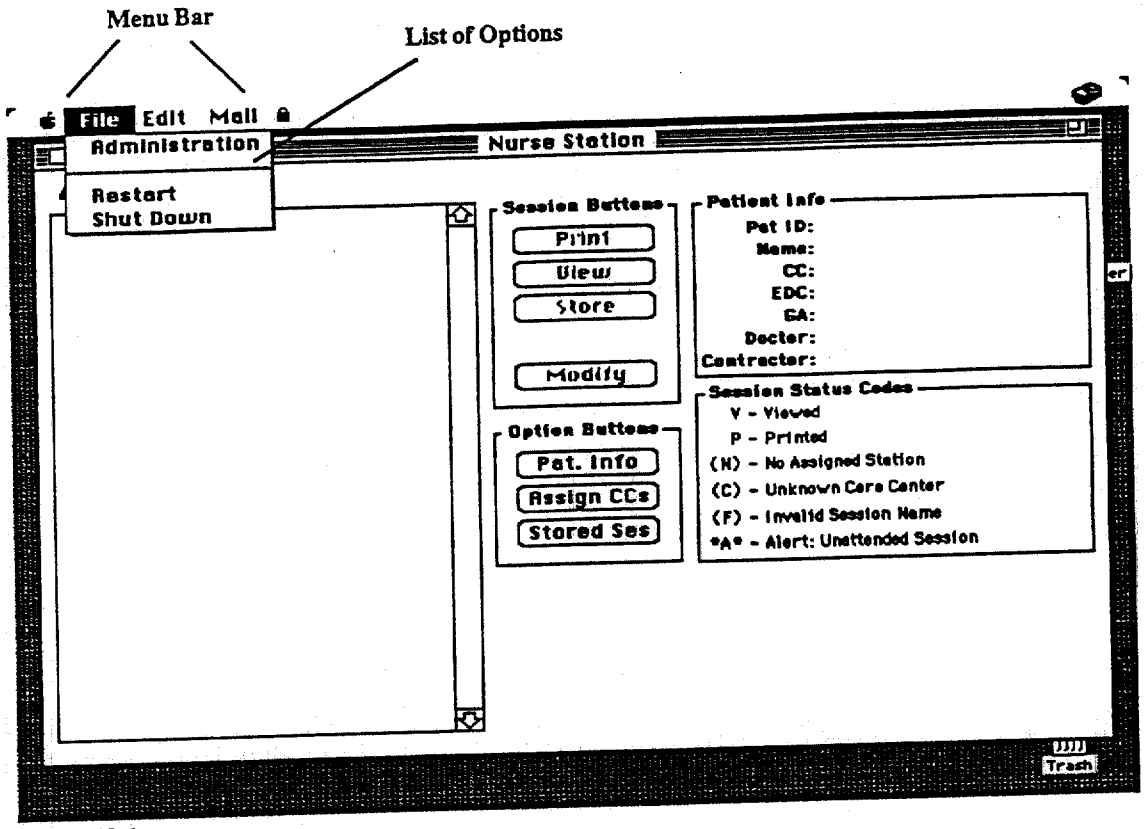


Figure 12-1
Menu Bar and File Menu Script

12.2 Drag the cursor to the "Restart" option and release the mouse.

12.3 A message window will appear and say "Are you sure you want to restart the computer" "Yes" or "No". If you are sure you want to restart, click the mouse on "Yes". This will automatically restart the computer.

12.3 Do not "Shut Down" the computer or select Administration unless instructed to do so.